

(19)

Europäisches Patentamt

European Patent Office

Office européen des brevets



(11)

EP 0 747 020 A2

(12)

EUROPEAN PATENT APPLICATION

(43) Date of publication:
11.12.1996 Bulletin 1996/50

(51) Int. Cl.⁶: A61F 2/06

(21) Application number: 96301021.0

(22) Date of filing: 14.02.1996

(84) Designated Contracting States:
AT BE CH DE DK ES FR GB GR IE IT LI LU MC NL
PT SE

(30) Priority: 07.06.1995 US 474269

(71) Applicant: Cook Incorporated
Bloomington Indiana 47402 (US)

(72) Inventors:
• Fearnot, Neal E.
West Lafayette, IN 47906 (US)

• Chuter, Timothy A.
216 44 Malmö (SE)
• DeBruyne, Michael P.
Bloomington, IN 47408 (US)

(74) Representative: Johnston, Kenneth Graham
Lucent Technologies (UK) Ltd,
5 Mornington Road
Woodford Green Essex, IG8 OTU (GB)

(54) Improved barb and expandable transluminal graft prosthesis for repair of aneurysm

(57) An improved prosthesis assembly (422) for placement at an aneurysm in the bifurcated lumen of the aorta and the common iliac arteries extending therefrom. The prosthesis assembly includes a single lumen graft (1) or a bifurcated lumen graft having a main body and ipsilateral and contralateral limbs extending therefrom. The main body and ipsilateral and contralateral limbs each have a spring assembly (12,31) about their orifices for conforming that portion of the graft to the wall of the vessel lumen. The main body spring assembly has an improved barb (10) with first (401) and second (414) attachment arms for securely anchoring the spring assembly to the vessel wall. The improved barb includes two forms of mechanical attachment such as, for example, a helical coil body (405) positioned around a spring assembly arm (15) and, secondly, a bonding material such as, for example, solder for fixedly attaching the coil and spring assembly arm. The attachment arms of the barb are positioned longitudinally along the spring assembly arm for engagement with the vessel wall without engaging each other when the spring assembly is in a collapsed condition. The ipsilateral and contralateral spring assemblies (31) also include the improved barb with only a single attachment arm for anchoring the spring assembly to the vessel wall.

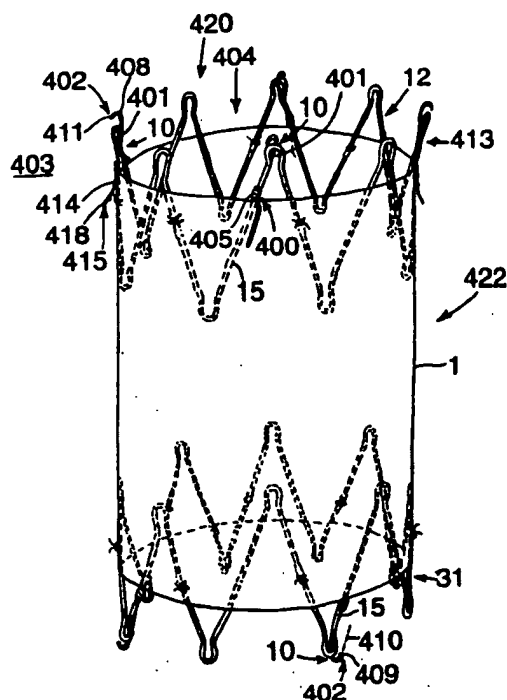


Fig. 53

EP 0 747 020 A2

Description

This application describes an improvement to U.S. Patent Application Serial No. 08/384,830, filed February 7, 1995, and EP- publication 0 539 237 A1.

The invention relates to an improved mechanism for enabling a transluminal graft prostheses to be implanted in a vascular system for the repair of aneurysms.

EP 0 539 237 A1 and U.S. Applications 782,696; 868,792; and 959,758 describe the problems of repairing aneurysms and is hereby referred to. It also describes related prior art.

Although ideally suited for its intended purpose, one problem noted during surgical placement of the prosthesis assembly of the present invention involved undesirable tension being exerted on the prosthesis assembly and in particular on the main spring assembly during release of the ipsilateral spring assembly in a bifurcated prosthesis assembly. In particular, the mooring loops attached to the main retainer assembly of the delivery assembly and the main spring assembly of the prosthesis assembly had been released, thus placing all the retention force on the main spring assembly of the prosthesis while the central elongated member was withdrawn to release the ipsilateral spring assembly. This undesirable retention force can dislodge the main spring assembly of the prosthesis or cause trauma to the wall of the aorta due to the barbs extending from the main spring assembly.

Another problem noted after surgical placement of the prosthesis assembly of the present invention involves the undesirable detachment of an anchoring barb from a spring assembly of the prosthesis assembly. In the past, these anchoring barbs have been affixed to the spring assembly by way of soldering, brazing, or welding. Various types of medical grade adhesives including epoxies have also been contemplated. A body fluid such as, for example, blood comes in contact with these affixed components and can, over time, degrade the bonding material. As a result, the two affixed components detach. A component separated from the prosthesis assembly can become mobile and cause complications such as embolisms, dissections, or other trauma to the vascular system. Such complications can become extremely serious and result in patient death. In addition, another problem with component detachment is that the prosthesis assembly can change position with respect to the aortic aneurysm, thereby subjecting the patient to the consequences of a ruptured aortic aneurysm.

Still another problem associated with the transluminal prosthesis assembly is migration thereof should the assembly not be securely anchored in the first instance. Diseased or weakened vessel walls can also dissect or rupture due to an inadequately anchored prosthesis, which can cause the prosthesis assembly to migrate. Such migration can also occur after initial placement due to blood flowing between the graft and vessel wall.

According to the present invention, there is pro-

vided a spring assembly as defined in claim 1, or a prosthesis assembly as defined in claim 8.

The foregoing anchoring and detachment problems are solved and a technical advance is achieved in an improved barb that is employed on the spring assembly of the transluminal graft prosthesis. To minimize, if not completely eliminate, detachment of the barb from the spring assembly, the barb includes a body that is mechanically positioned around an arm of the spring assembly. As a further margin of safety, the mechanical attachment of the barb body and spring assembly are fixedly attached with, for example, solder or another bonding material. Should the bonding material be degraded, the mechanical attachment of the barb body and spring assembly arm provides a second, back-up mode of attachment. Furthermore, the improved barb has a first attachment arm extending longitudinally from the body with an end that is positioned toward an exterior of the spring assembly and prosthesis.

In a preferred embodiment of the improved barb, the body includes a helical coil having a passage with an arm of the spring assembly extending longitudinally therethrough. The first attachment arm extends longitudinally from one end of the spring material and through an open end of the spring assembly. Advantageously, the helical coil is further fixedly attached to the spring assembly arm with a bonding material such as, for example, solder. The first attachment arm of the improved barb extends longitudinally along the spring assembly arm and in the interior of the spring assembly. A hook is included about the end of the first attachment arm so as to position the end of the arm for securely engaging the vessel wall in the placement procedure. To advantageously ensure placement of the attachment arm, the hook end of an upstream barb includes a beveled surface with a sharp point for penetrating the vessel wall.

To advantageously solve the problem of securely anchoring the barb to the vessel wall, the improved barb includes a second attachment arm extending longitudinally along the spring assembly arm and in a direction opposite to the first attachment arm. The first and second attachment arms extend from opposite ends of the helical coil. The second attachment arm also extends outwardly away from the spring assembly arm to engage the vessel wall and further penetrate it should any downstream motion of the prosthesis assembly occur. One end of the second attachment arm is further inclined away from the spring assembly to more easily engage the vessel wall. The second attachment arm advantageously provides a second anchoring mechanism for the barb should any downstream migration of the prosthesis assembly occur. The end of the second attachment arm is beveled as is the first attachment arm to present a sharp point and pierce the vessel wall.

The improved barb positioned on the downstream spring assembly is similar to the upstream barb except that the second attachment arm is normally not utilized. To prevent undesired trauma to the vessel wall, the end

of the first attachment arm of the downstream barb includes a flat, blunt surface.

The improved barb is utilized in an improved prosthesis assembly advantageously including a single lumen graft or a bifurcated graft should the prosthesis be needed to support an aneurysm positioned near the bifurcation of the aorta at the ipsilateral and contralateral iliac arteries.

The foregoing retention problem is solved and a technical advance is achieved in an improvement to the transluminal arrangement of the present invention. The improvement includes substituting for the stent boot of the transluminal arrangement a sheath having a longitudinal bore that closely approximates the cross-sectional shape of the elongated member of the delivery assembly and is slidably and longitudinally positioned around the elongated member of the delivery assembly. The bore of the sheath closely approximates the cross-sectional shape of the elongated member to advantageously minimize blood flow therethrough. The bore at and in the vicinity of the cranial end of the sheath is enlarged to receive one end of the prosthesis assembly.

A further improvement in the transluminal arrangement is the inclusion of a slit extending longitudinally from one end of the sheath, which is adapted to slide the sheath along the elongated member and release the one end of the prosthesis assembly. Movement of the sheath with respect to the elongated member of the delivery assembly advantageously maintains the prosthesis assembly in a fixed relative position without undue tension being placed on the prosthesis assembly.

Another improvement in the transluminal arrangement includes an annular groove about the caudal end of the sheath in which a fastener is positioned therein to maintain the longitudinal slit in a closed position. The fastener such as a suture material tie is cut to allow the slit of the sheath to be opened. The elongated member of the delivery assembly is positioned through this slit so as to slide the sheath caudally along the elongated member and release the one end of the prosthesis assembly without any undue tension being placed on the prosthesis assembly.

For purposes of radiographic visualization, the sheath includes a radiopaque material such as a polyether block amide elastomer.

Another improvement in the transluminal arrangement includes visual markers positioned longitudinally on the elongated member of the delivery assembly. These markers are also positioned distally and proximally of the prosthesis assembly to indicate advantageously the orientation of the prosthesis assembly in the transluminal arrangement during the prosthesis placement procedure.

The present invention provides a transluminal graft prosthesis that can be safely and precisely positioned.

An object of the present invention is to provide a prosthesis for the safe repair of aneurysms without the risks associated with invasive surgical repair.

It is another object of the invention to provide a cou-

pling between a plurality of spring expanding assemblies that provides a relatively flexible prosthesis during insertion, a relatively rigid prosthesis after attachment, and also maintains the alignment of the springs when the prosthesis is compressed by an extrusion device applied to one end.

The present invention provides a device for transluminal grafting of a prosthesis in a lumen, comprising: a tubular introducer sheath having a longitudinal bore; a prosthesis comprising a tubular graft having a longitudinal bore and disposed in the longitudinal bore of the tubular introducer sheath, the graft being expandable radially to substantially conform to the interior wall of a lumen; a spring expanding assembly permanently attached to the tubular graft to expand the graft so that it substantially conforms to the interior wall of a lumen when the graft is removed from the introducer sheath; an anchoring means for permanently attaching the graft to an interior wall of a lumen; a tubular carrier means having a longitudinal bore and disposed in the longitudinal bore of the tubular graft, the tubular carrier means provided with a plurality of apertures; a central control means for maintaining the axial position of the prosthesis during removal of the introducer sheath, the central control means disposed in the longitudinal bore of the tubular carrier means; and mooring loops engaging the prosthesis and passing through the apertures in the tubular carrier means to engage the central control means.

The present invention also provides a method for engrafting a prosthesis in a lumen comprising the steps of a) providing an access to the lumen; b) providing a device for engrafting the prosthesis comprising: a tubular introducer sheath having a longitudinal bore; a tubular graft having a longitudinal bore and disposed in the longitudinal bore of the tubular introducer sheath, the graft being expandable radially to substantially conform to the interior wall of a lumen; a spring expanding assembly permanently attached to the tubular graft to expand the graft so that the graft substantially conforms to the interior wall of a lumen when the graft is removed from the introducer sheath; an anchoring means for permanently attaching the graft to an interior wall of a lumen; a tubular carrier means having a longitudinal bore and disposed in the longitudinal bore of the tubular graft, the tubular carrier means provided with a plurality of apertures; a central control means for maintaining the axial position of the prosthesis during removal of the introducer sheath, the central control means disposed in the longitudinal bore of the tubular carrier means; mooring loops engaging the prosthesis and passing through the apertures in the tubular carrier means to engage the central control means; c) inserting the device and urging the device into a lumen to a desired location within the lumen; d) withdrawing the tubular introducer sheath to expose the graft; e) disengaging the central control means from the mooring loops; and f) removing the tubular introducer sheath, carrier means, and central control means.

The present invention provides an occlusive umbrella comprising: a spring expanding assembly having a proximal and a distal end; barbs attached to the proximal end of the spring means; a tubular graft having a longitudinal bore and having a proximal end and a distal end, the tubular graft open at the proximal end and closed at the distal end, the graft attached to the spring; a dilator having a distal end and a proximal end, the proximal end of the dilator attached to the distal end of the tubular graft; a first tubular catheter having a proximal end, a distal end, and a longitudinal bore, the first tubular catheter inserted into the longitudinal bore of the graft and attached to the proximal end of the dilator; a second tubular catheter having a proximal end, a distal end, and a longitudinal bore, the distal end of the second catheter communicating with the proximal end of the first catheter; a flexible rod having a proximal end and a distal end, the distal end of the flexible rod inserted into the longitudinal opening of the first catheter and the longitudinal opening of the second catheter, the distal end of the flexible rod contacting the dilator head.

The foregoing problems are solved and a technical advance is achieved in an illustrative prosthesis for repairing an aneurysm. The prosthesis comprises a bifurcated endovascular graft having a main body and first and second limbs extending therefrom. The main body includes a main bore extending longitudinally therein and having a cranial orifice. The first limb includes a first bore extending longitudinally therein, communicating with the main bore, and having a first caudal orifice. The second limb includes a second bore extending longitudinally therein, communicating with the main bore and having a second caudal orifice. The prosthesis also comprises a first imageable marker extending longitudinally along the first limb and a second imageable marker extending longitudinally along the second limb and spaced at least a predetermined distance away from the first marker.

The invention also comprises an illustrative prosthesis delivery system for percutaneously inserting the prosthesis in an aneurysm. The delivery system comprises a tubular introducer sheath having a sheath bore extending longitudinally therein and a central carrier coaxially positionable within the sheath bore of the sheath. The central carrier includes a head region having a dimension approximating said sheath bore, a shaft region having a dimension approximating the sheath bore, and a stem region positioned between the head and shaft regions and having a dimension smaller than the sheath bore for positioning the prosthesis therearound and in the sheath bore.

The present invention also includes an illustrative method of inserting a bifurcated prosthesis in an aneurysm utilizing the prosthesis delivery system. The method comprises the steps of percutaneously obtaining cross access with a first guide between femoral arteries positioned caudal to the aneurysm; percutaneously obtaining access to a lumen of the aneurysm with

the second guide; and positioning the prosthesis in the aneurysm and one limb thereof in one of the femoral arteries with the prosthesis delivery system and the second guide. The method also comprises the steps of positioning another limb of the prosthesis in the other of the femoral arteries with the first guide and releasing the prosthesis from the delivery system when the prosthesis is positioned in the aneurysm.

The invention is described in greater detail below based on a few selected embodiments. Those skilled in the art will appreciate that the prosthesis according to the invention can be applied in various modifications.

Brief Description of the Drawing

Figs 1 to 49 are described in EP 0539237 A1.

FIG. 50 depicts a partially sectioned view of an improvement in the transluminal arrangement of FIG. 43;

FIG. 51 depicts a partially sectioned view of ipsilateral limb spring assembly of the prosthesis assembly and the tubular sheath of the transluminal arrangement of FIG. 50;

FIG. 52 depicts the tubular sheath of FIG. 50 with the elongated member of the arrangement positioned through a slit at the caudal end of the tubular sheath;

FIGS. 50 to 52 forming the subject of U.S. Patent Application No. 384,830;

FIG. 53 depicts an improved prosthesis assembly of the present invention with improved barbs on the spring assemblies positioned at opposite ends of the transluminal graft;

FIG. 54 depicts an enlarged front view of the improved barb and a portion of the spring assembly of FIG. 53;

FIG. 55 depicts a side view of the improved barb and spring assembly of FIG. 54;

FIG. 56 depicts a further enlarged view of the improved barb of FIG. 55; and

FIG. 57 depicts an enlarged front view of the improved barb and a portion of the downstream spring assembly of FIG. 53.

Depicted in FIG. 50 is an improvement to transluminal arrangement 350 for positioning prosthesis assembly 228 at a particular position in a bifurcated lumen. As previously described with respect to FIGS. 43-45, transluminal arrangement 350 includes a main or outer sheath 217 for containing main spring assembly 301 in a compressed state, a stent boot sheath 304 for containing ipsilateral spring assembly 302 in a compressed state, and stent boot sheath 305 for containing a contralateral spring assembly 303 in a compressed state. The transluminal arrangement also includes retainer assembly 351 positioned in the main and ipsilateral bores of the graft for retaining the prosthesis assembly in the bifurcated lumen while outer sheath 217 is withdrawn from the prosthesis assembly. As a result, the

main spring assembly is released from its collapsed state. However, a problem with transluminal arrangement 350 of FIGs. 43-45 is that the prosthesis assembly 228 and in particular main spring assembly 301 can be pulled caudally and undesirably repositioned when vain retainer assembly 351 and in particular elongated member 352 is pulled caudally to release ipsilateral spring assembly 302 from stent boot sheath 304.

In order to overcome this problem, the stent boot sheath of the transluminal arrangement has been improved to include tubular sheath 362. The tubular sheath includes a longitudinal bore 363 and is now slidably and longitudinally positioned around elongated member 352 and in particular outer catheter 318. Bore 363 of the tubular sheath approximates the diameter of elongated cylindrical member 352 to minimize blood flow therethrough, but allows the sheath to slide along the elongated cylindrical member to release ipsilateral spring assembly 302 of the prosthesis assembly. The bore of the tubular sheath at and in the vicinity of cranial end 364 of the tubular sheath is enlarged to receive caudal end 372 of the prosthesis assembly and, in particular, ipsilateral spring assembly 302 positioned thereat. To radiographically visualize tubular sheath 364 during the prosthesis placement procedure, the tubular sheath includes a radiopaque material such as a polyether block amide nylon 12 elastomer.

The improvement of transluminal arrangement 350 further includes slit 365 extending longitudinally in tubular sheath 362 from caudal end 366 thereof. In order to maintain the fixed relative position of tubular sheath 362 with respect to outer catheter 318, another improvement includes a plurality of annular ridges and grooves 369, that are positioned adjacent caudal end 369 of the tubular sheath. A fastener such as suture material 368 is tied around the tubular sheath and in annular groove 367 of the plurality. The tied suture material in annular groove 367 maintains longitudinal slit 365 in a closed position around outer catheter 318. When the physician desires to expand ipsilateral spring assembly 302, tied suture material 368 is cut allowing the caudal end of the tubular sheath to be spread apart along the longitudinal slit 365.

FIG. 52 depicts caudal end 369 of tubular sheath 362 split apart along longitudinal slit 365 with outer catheter 318 extending through the slit. As a result, tubular sheath 362 can be slid caudally along outer catheter 318 to release ipsilateral spring assembly 302. This advantageously permits the release of ipsilateral spring assembly 302 without undue tension on the prosthesis assembly and in particular main spring assembly 301. Main retainer assembly 351 is maintained in a fixed position, which in turn maintains the position of the prosthesis assembly with mooring loops 357 and 358 looped around main spring assembly 301 and mooring loops 314 and 317 positioned around ipsilateral spring assembly 302. These mooring loops are positioned through elongated member 352, which is maintained in a fixed position when sliding tubular sheath 362 thereo-

ver. As a result, the prosthesis assembly is maintained at the desired position in the aorta and bifurcated iliacs without having to reposition the prosthesis assembly due to movement of the assembly during the positioning procedure.

Still another improvement in transluminal arrangement 350 is the inclusion of longitudinal markers 370 and 371 positioned on carrier shaft region 360 and dilator head 351, respectively. These longitudinal markers positioned on elongated member 352 provide the physician with a visual indication of the orientation of prosthesis assembly 228 during the surgical placement procedure. These longitudinal markers are depicted in FIGs. 50 and 52. To further stabilize the position of main spring assembly 301 and ipsilateral spring assembly 302, the previously described circular apertures 355, 356, 320 and 321 are now closely spaced transverse slots 374, 375, 372 and 373, respectively. These closely spaced slots more readily maintain the equal lengths of mooring loops 357, 358, 314 and 317 so as to maintain more even retention pressure on main spring assembly 301 and ipsilateral spring assembly 302. As a result, the prosthesis assembly 228 is better maintained in a relatively fixed position during the placement procedure with undesirable movement being minimized.

FIG. 53 depicts an improved prosthesis assembly 422 including transluminal graft 1 with upstream and downstream spring assemblies 12 and 31 positioned at opposite ends thereof. Each of the spring assemblies includes one or more barbs 10 which include improvements thereto for more securely anchoring the prosthesis assembly to a vessel wall. The improvement in barb 10 includes a body 400 mechanically positioned around an arm 15 of the spring assembly. Preferably, body 400 includes a helical coil 405 having a passage extending longitudinally therethrough. Spring assembly arm 15 is positioned through the passage of the helical coil, which provides a first mechanical attachment of the barb to the spring assembly. The helical coil body is also fixedly attached to the spring assembly arm via solder, which is applied to the helical coil body and the spring assembly arm. The solder provides a second means for attaching the barb to the spring assembly. Should body fluids dissolve or erode the solder, the mechanical positioning of the spring assembly arm through the passage of the helical coil body maintains the interconnection thereof.

The barb also includes a first attachment arm 401 extending longitudinally along the spring assembly arm and in interior 404 of the spring assembly. Furthermore, the first attachment arm extends through open end 420 of the spring assembly with end 402 positioned toward exterior 403 of the spring assembly for anchoring to a vessel wall. The attachment arm extends longitudinally along the spring arm so as to change its vertical orientation with the spring arm as the spring assembly expands from its collapsed condition. This orientation also prevents the barb attachment arm from inadvertently interacting or engaging another barb or portion of the spring assembly when the spring assembly is in the

collapsed condition or expanding therefrom.

To further position the barb, the end of the barb is positioned toward exterior surface 413 of the spring assembly for anchoring in the vessel wall. Since blood flows through the graft from upstream spring assembly 12 to downstream spring assembly 31, first attachment arm 401 includes a hook 408 positioned about the end thereof. This further positions the attachment arm into the vessel wall and more securely anchors the spring assembly to the vessel wall should the prosthesis assembly attempt to migrate downstream.

To further secure the barb in the vessel wall, end 402 of the attachment arm includes a beveled surface 411 for entering the vessel wall. This beveled surface provides a sharp point for piercing the vessel wall and securely anchoring hook 408 therein.

To further secure the prosthesis and spring assemblies to the vessel wall, barb 10 includes a second attachment arm 414 extending longitudinally from the helical coil body in a downstream direction, which is opposite in direction to that of first attachment arm 401. Similar to the first attachment arm, the second attachment arm includes an end 415 positioned toward the exterior of the spring assembly. End 415 also includes a beveled surface 418 for piercing the vessel wall and securing the second attachment arm therein. The second attachment arm also extends longitudinally along the spring assembly arm; however, the second attachment arm extends exterior to the spring assembly, unlike the first attachment arm. The second attachment arm is also inclined outwardly away from spring assembly arm 15 to more easily engage the vessel wall and to provide a spacing for inserting the graft material between the second attachment arm and spring assembly arm.

Downstream spring assembly 31 also includes improved barb 10. Barb 10 of the second spring assembly is very similar to that of the upstream spring assembly; however, the second attachment arm is not normally provided. Furthermore, end 402 of the attachment arm includes a flat surface 409 which is transverse to longitudinal axis 410 of the first attachment arm. A plurality of barbs 10 are positioned on spring assembly arms 15 of the downstream spring assembly to engage the vessel wall; however, the beveled surface is not required to pierce the vessel wall surface.

FIG. 54 depicts an enlarged view of a portion of spring assembly 12 with improved barb 10 positioned around spring arm 15. Two spring assembly arms 15 are depicted with recurved arch 42 interconnecting them. The spring assembly is normally formed from a single continuous wire formed into a zig-zag pattern as previously described with the ends of the wire interconnected. Spring arm 15 extends through passage 406 of helical coil 405. Solder 407 forms a second means of fixedly attaching the barb to the spring assembly arm. First attachment arm 401 extends longitudinally along the spring assembly arm and on the back side of the arm or interior of the spring assembly. The first attach-

ment arm also includes a hook 408 about end 402 of the attachment arm. The barb also includes a second attachment arm 414 extending longitudinally along the spring assembly arm 15 in a direction opposite to that of the first attachment arm.

FIG. 55 depicts a side view of the improved barb 10 of FIG. 54 positioned on spring assembly arm 15. This side view better depicts hook 408 positioned about end 402 of first attachment arm 401. End 402 of this arm with beveled surface 411 extends toward exterior 403 of the spring assembly. Second attachment arm 414 also extends toward exterior 403 of the spring assembly; however, the second arm is on the exterior or outside of the spring assembly rather than the inside or interior of the spring assembly as is first arm 401. Second attachment arm includes a beveled surface 418 at end 415. End portion 416 is more steeply inclined from the spring assembly than remaining portion 417 of attachment arm 414. The angle between the end portion and remaining portion of the attachment arm is approximately 150 degrees. This inclination away from the spring assembly allows the second attachment arm to readily pierce the vessel wall and embed itself therein.

Depicted in FIG. 56 is a further enlarged view of improved barb 10 of FIG. 55. Body 400 of the barb is clearly depicted as a helical coil 405 with passage 406 extending longitudinally therethrough. First and second attachment arms 401 and 414 extend from ends 419 and 421 of the coil, respectively. Hook 408 is positioned about end 402 of the attachment arm with opening 412 for securing the vessel wall therein. Beveled surface 411 is also shown for further piercing the vessel wall. Second attachment arm 414 extends from coil end 421 and is inclined away from the longitudinal axis of coil passage 406. End portion 416 of the attachment arm is angled more steeply than remaining portion 417. End 415 of the second arm includes beveled surface 418 for piercing the vessel wall.

FIG. 57 depicts an enlarged partial view of downstream spring assembly 31 with barb 10 positioned around spring assembly arm 15. As previously described, this second barb is very similar to upstream barb 10; however, the barb does not normally include a second attachment arm. Rather, the barb includes only a first attachment arm 401 as previously described. However, end 402 of the attachment arm includes a flat surface 409, which is transverse to the longitudinal axis of the attachment arm.

Although prosthesis assembly 402 of FIG. 53 has been described as a single lumen graft 1, the prosthesis assembly including the improved barbs can be included in prosthesis assembly 228 with bifurcated graft 206. As previously described, the bifurcated graft includes a cranial spring assembly 301 and first and second caudal spring assemblies 302 and 303. Improved barbs 10 are included on the upstream cranial spring assembly, whereas the improved barbs with a single first attachment arm are positioned on the first and second caudal spring assemblies.

The improved barbs more securely anchor the prosthesis assembly to the vessel wall while significantly lessening the opportunity for detachment from the spring assembly. At least two forms of fixation to the spring assembly are provided with the barb. The helical coil body provides a first mechanical attachment. A second means of attachment such as solder 407 also fixes the helical coil body and spring assembly arm together.

Claims

1. A spring assembly (12) for supporting a transluminal graft (1), within a lumen when said assembly is in an expanded operative condition, wherein the spring assembly comprises a barb arrangement (10) with a body (400) having a part (405) thereof attached to an arm (15) of the spring assembly, and having a member (401) extending from the said part and comprising a barb (408) which extends toward the exterior (403) of the assembly when the latter is in the operative condition.
2. An assembly according to claim 1, wherein the member extends longitudinally along and adjacent to the arm of the assembly, and in the interior of the assembly.
3. An assembly according to claim 2, wherein the said part of the body is a coil (405) with a passage (406) through which the said arm extends and to which the said member is fixedly attached, and wherein the said member extends from the coil.
4. An assembly according to claim 2 or 3, wherein the barb is a hook (408) formed on the distal end of the said member, said hook having a bevelled surface transverse to the longitudinal axis of the said member.
5. An assembly according to claim 1,2,3 or 4, wherein the barb arrangement further comprises a second member (414) extending from the said part and having a barb (418) extending toward the exterior of the spring assembly.
6. An assembly according to claim 5, wherein the second member extends longitudinally along the arm of the spring assembly and exterior thereto, and in a direction opposite to that of the first mentioned member.
7. An assembly according to claim 6, wherein the second member is inclined outwardly from the said arm and has an end which is more steeply inclined and which is bevelled.
8. A surgical device comprising a transluminal graft for implanting in a lumen, and a spring assembly according to any one of claims 1 to 7, wherein the

assembly is to be located at the upstream end of the graft.

9. A device according to claim 8, wherein another assembly according to any one of claims 1 to 4 is to be located at the distal end of the graft.
10. A surgical device comprising a transluminal graft for implanting in a lumen, and a spring assembly according to any one of claims 5 to 7, wherein the assembly is to be located at the upstream end of the graft, and wherein the graft is to be located within the second member (414).
11. In a transluminal graft (1;206) having a spring assembly (12,31;301.302,303) with a barb (10;205), an improvement in the barb comprising:

a helical coil (405) having a passage (406) with an arm (15) of the spring assembly extending longitudinally therethrough and a first attachment arm (401) extending longitudinally from one end (419) of the helical coil and through an open end (420) of the spring assembly, wherein the coil is attached to the spring assembly arm, the first attachment arm extends longitudinally along the spring assembly arm and in an interior (404) of the spring assembly, and an end (402) of the first attachment arm is positioned toward an exterior (403) of the spring assembly.

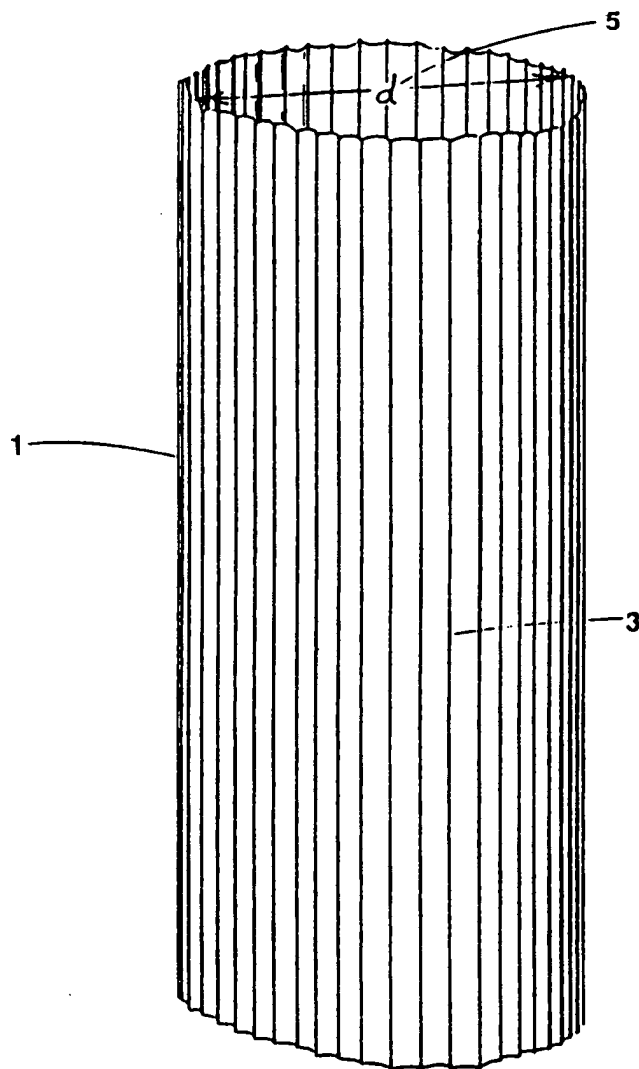


Fig. 1

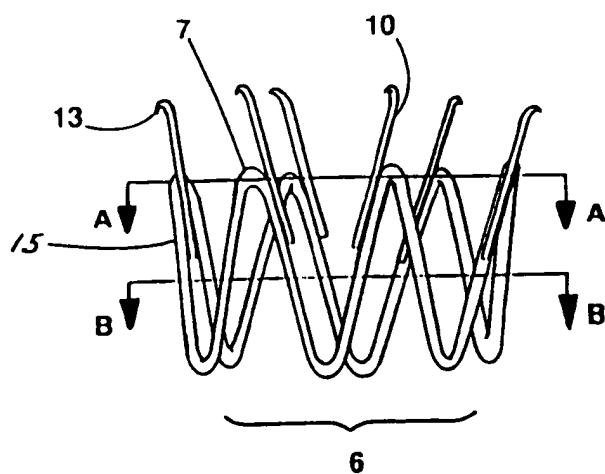


Fig. 2

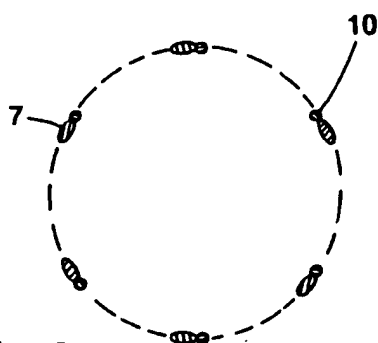


Fig. 3

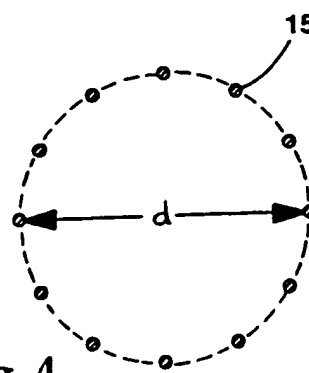


Fig. 4

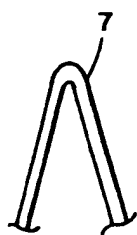


Fig. 5A

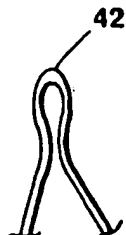


Fig. 5B

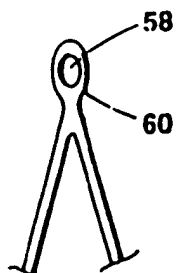


Fig. 5C

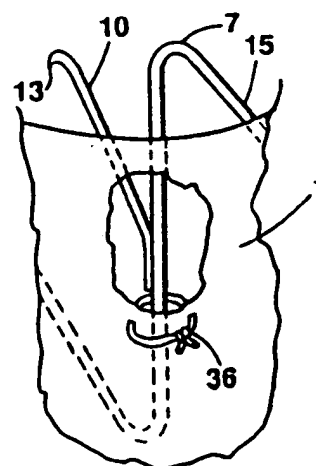


Fig. 6

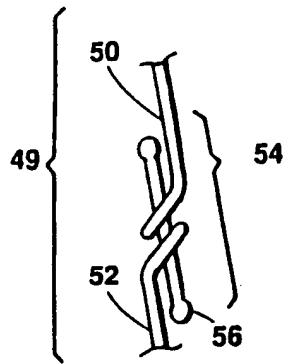


Fig. 7

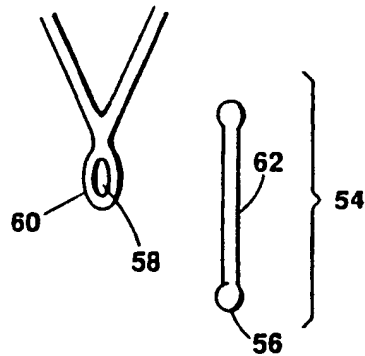


Fig. 8

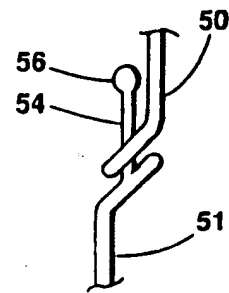


Fig. 10

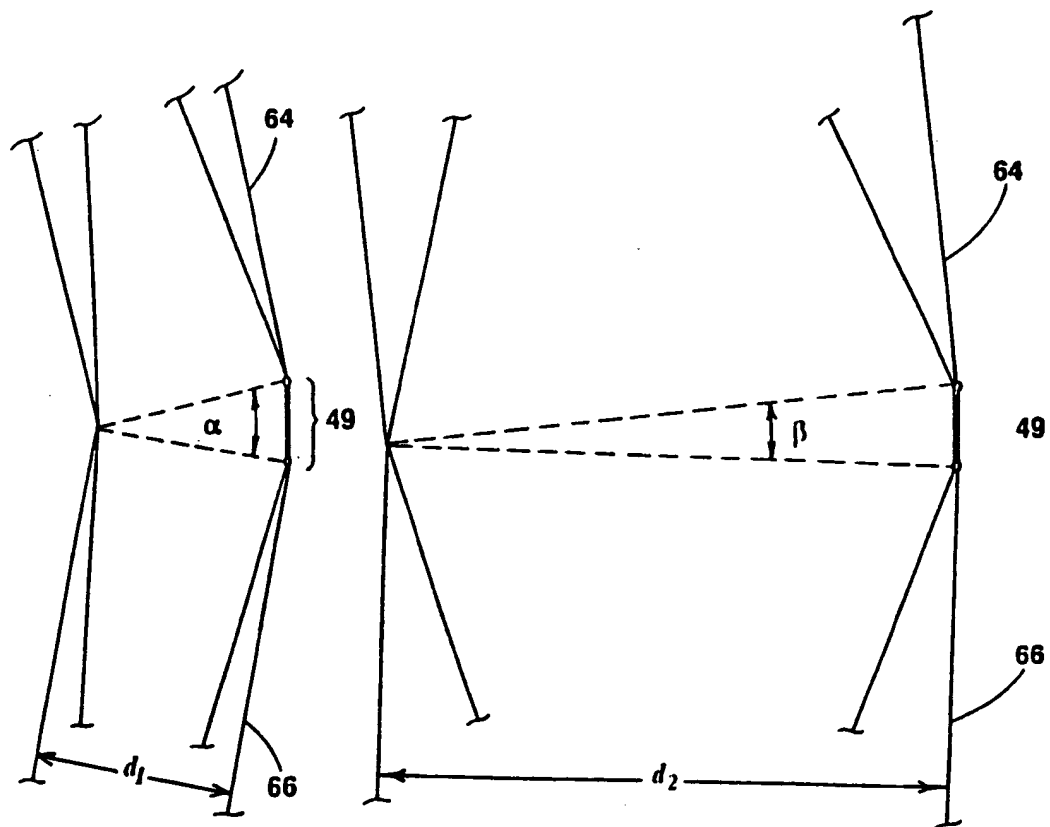


Fig. 9A

Fig. 9B

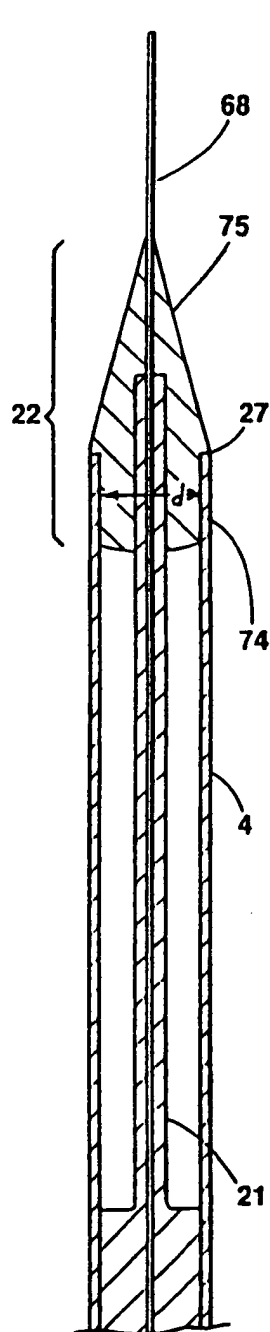


Fig. 11

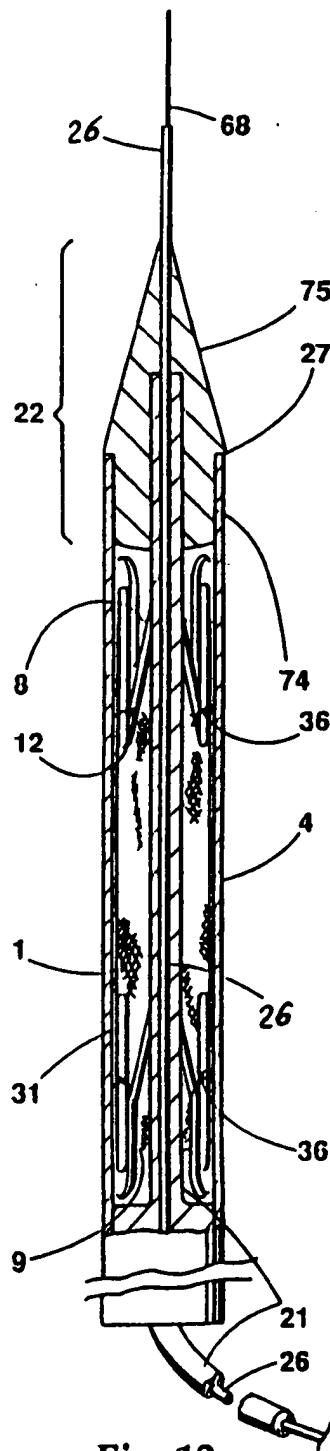


Fig. 12

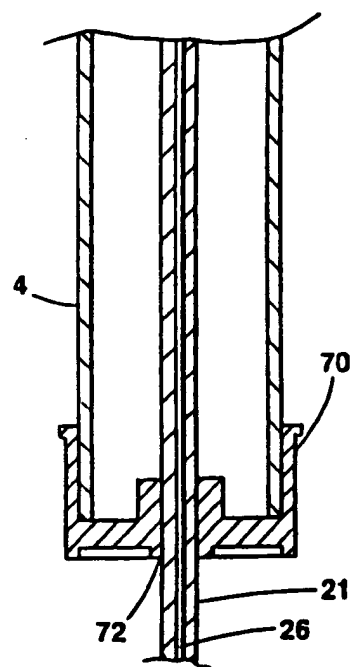


Fig. 13

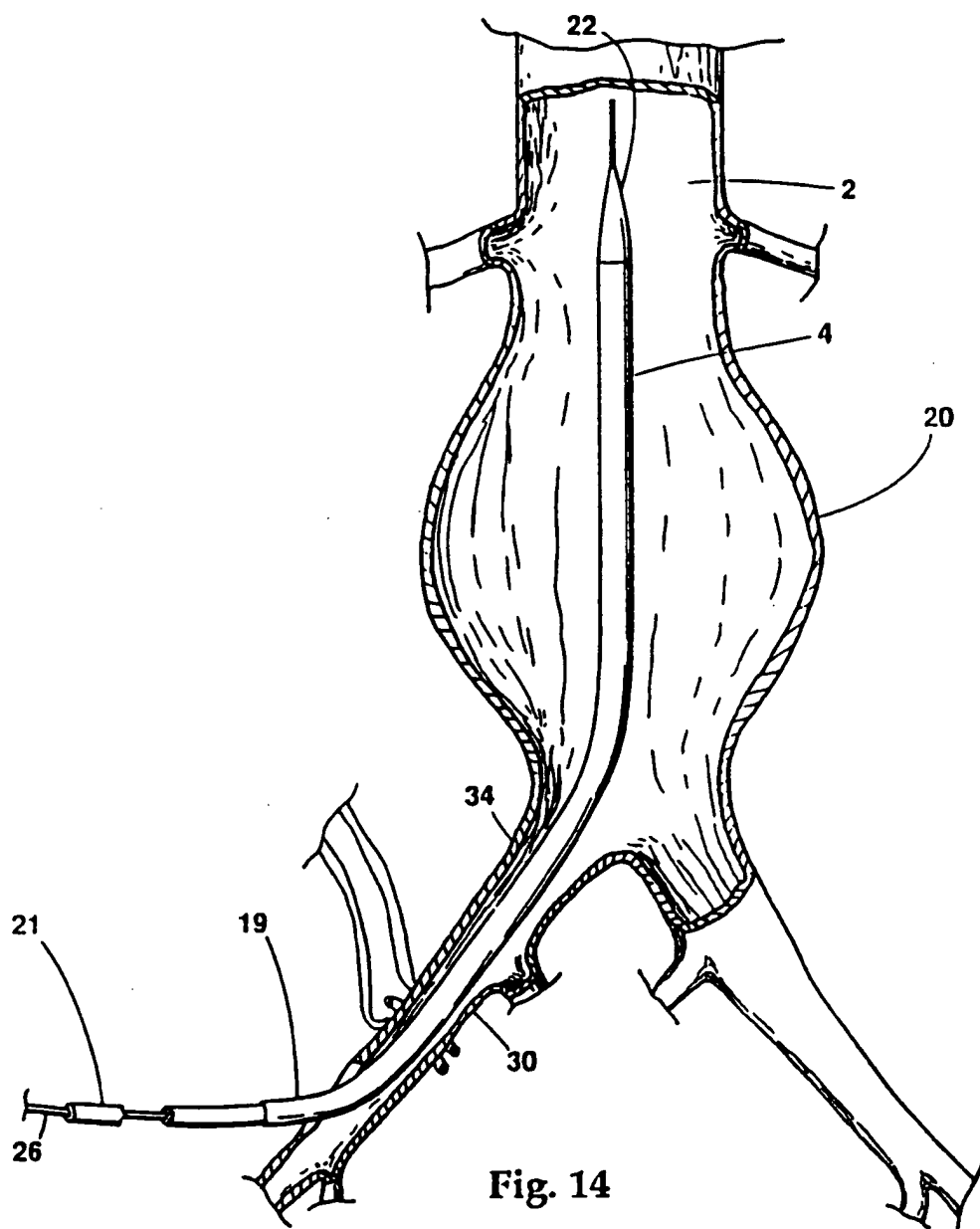


Fig. 14

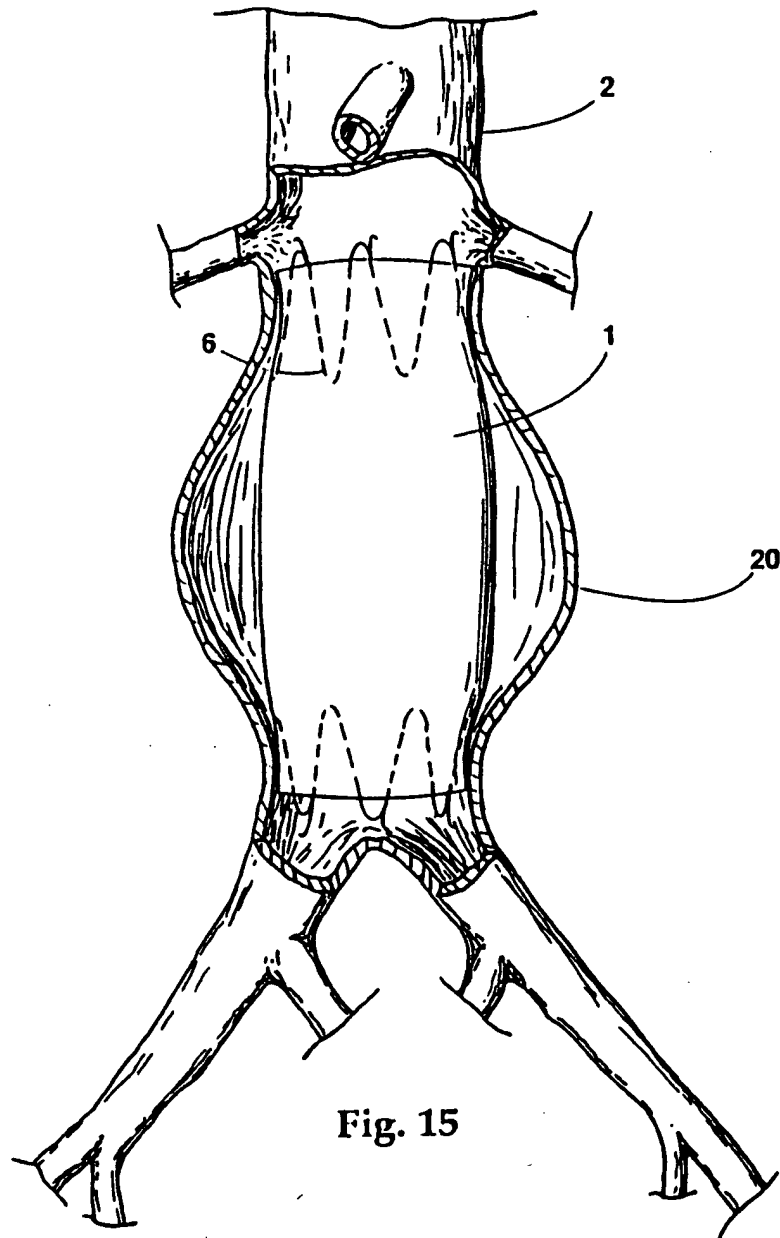


Fig. 15

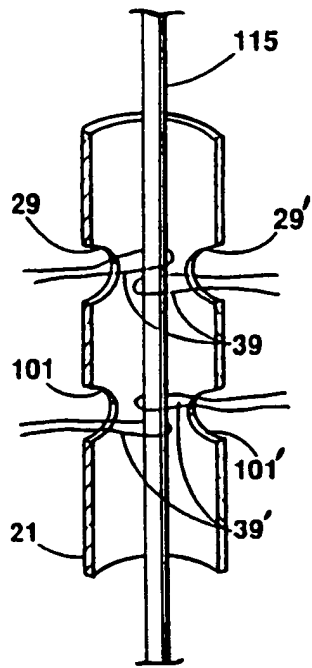


Fig. 16

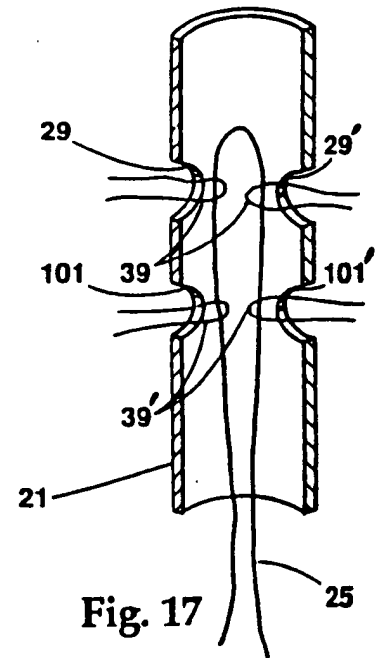


Fig. 17

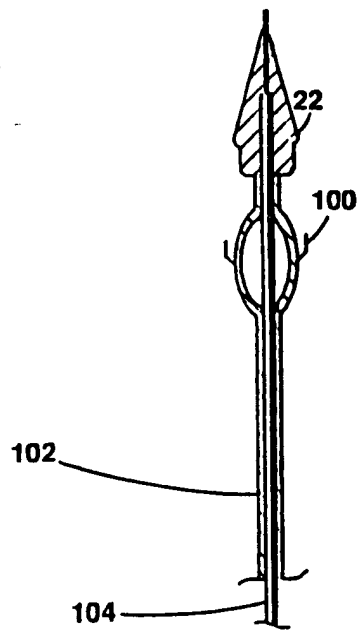


Fig. 18

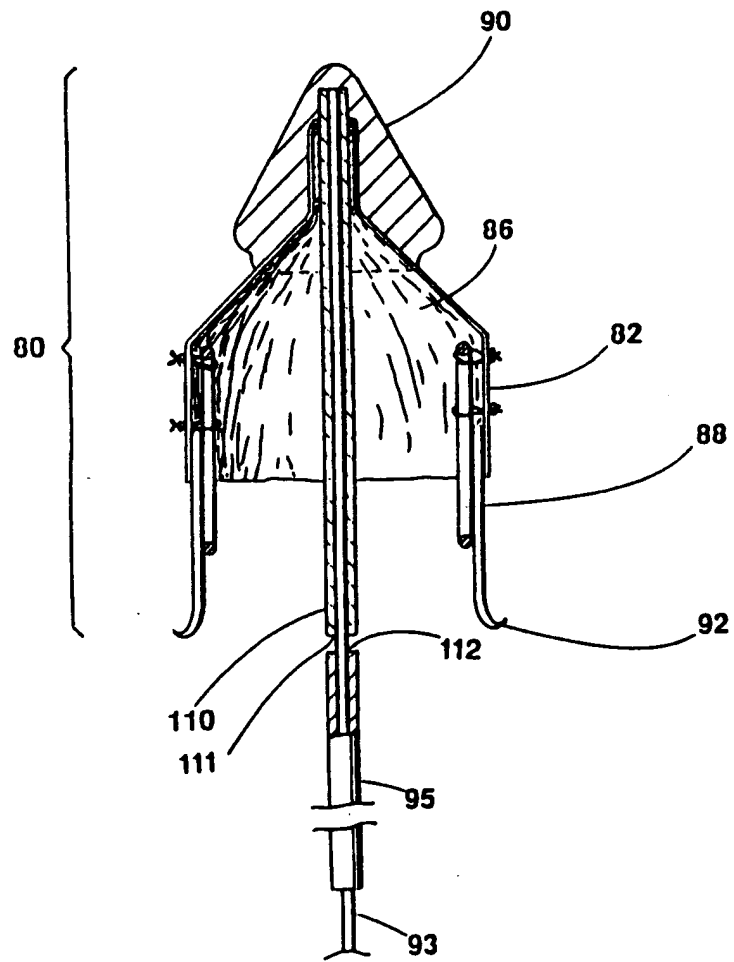


Fig. 19

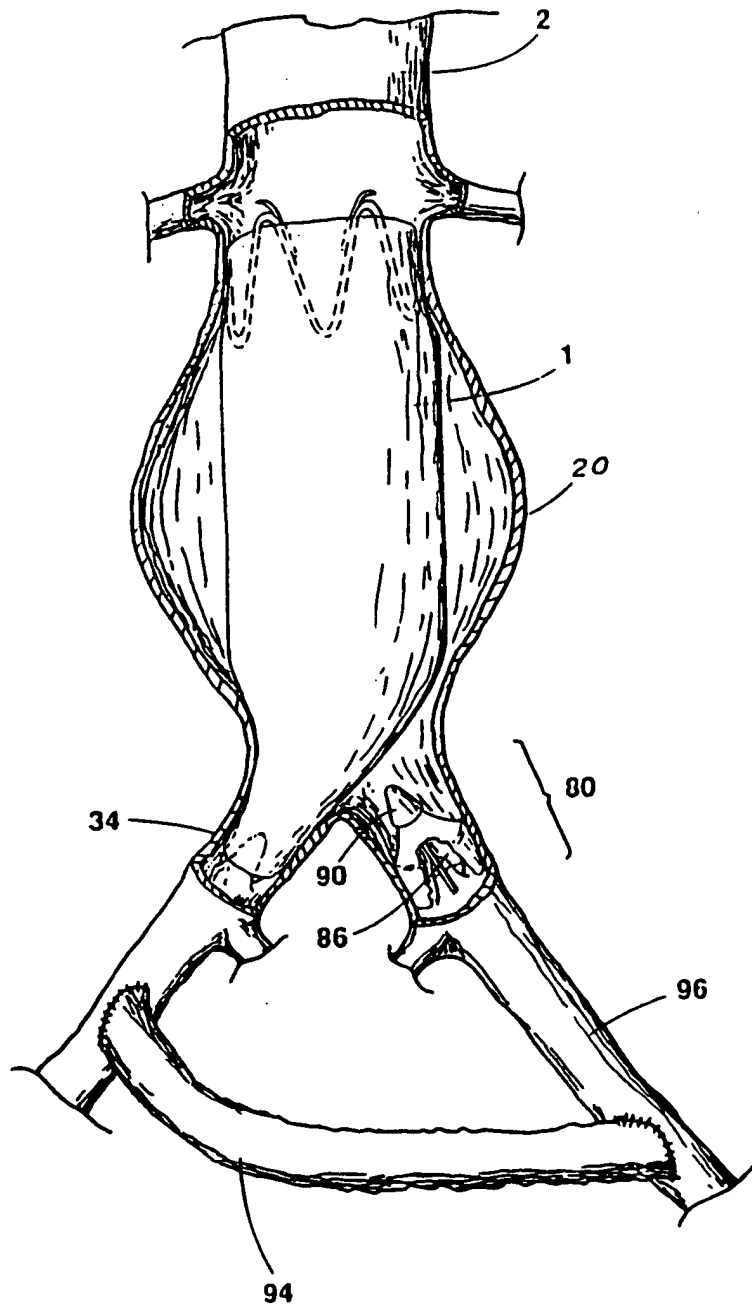
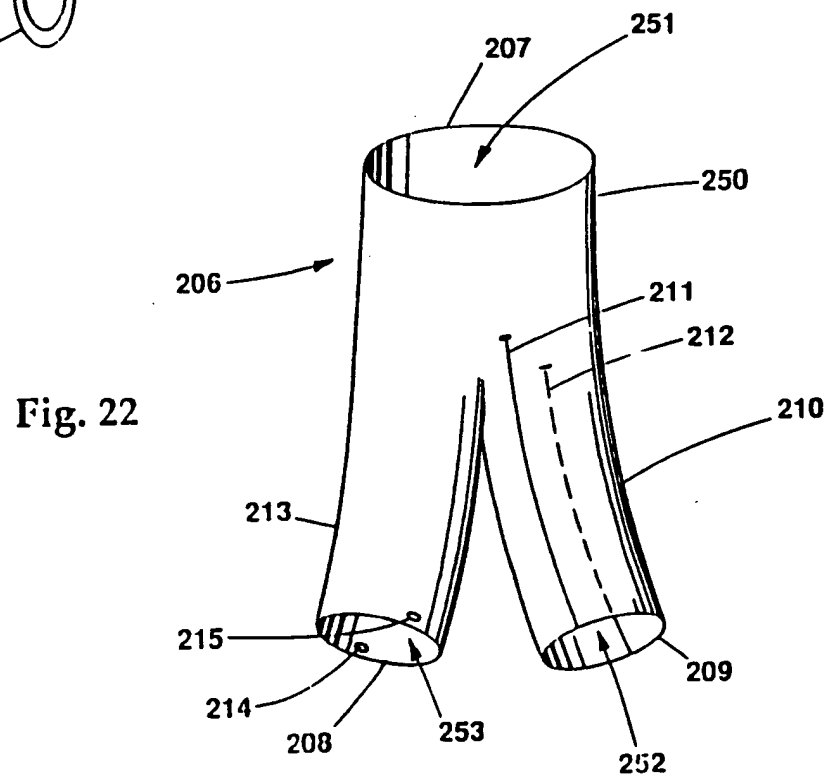
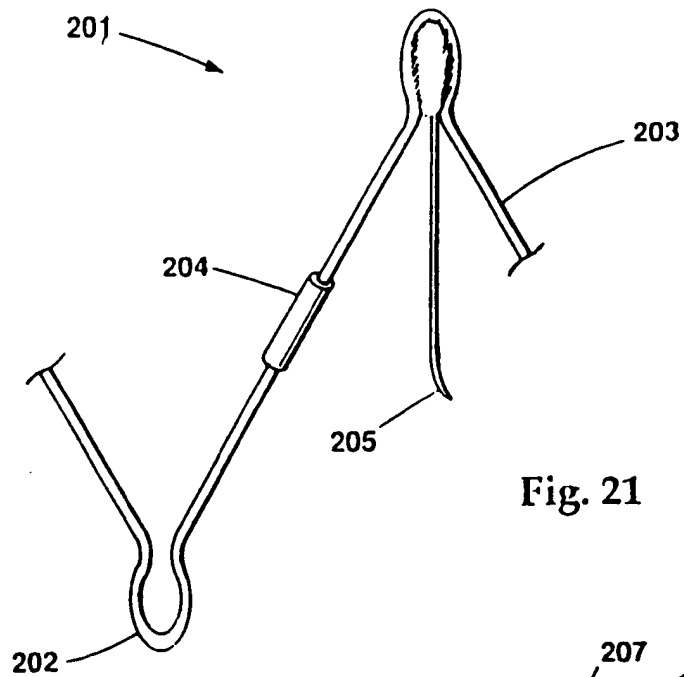
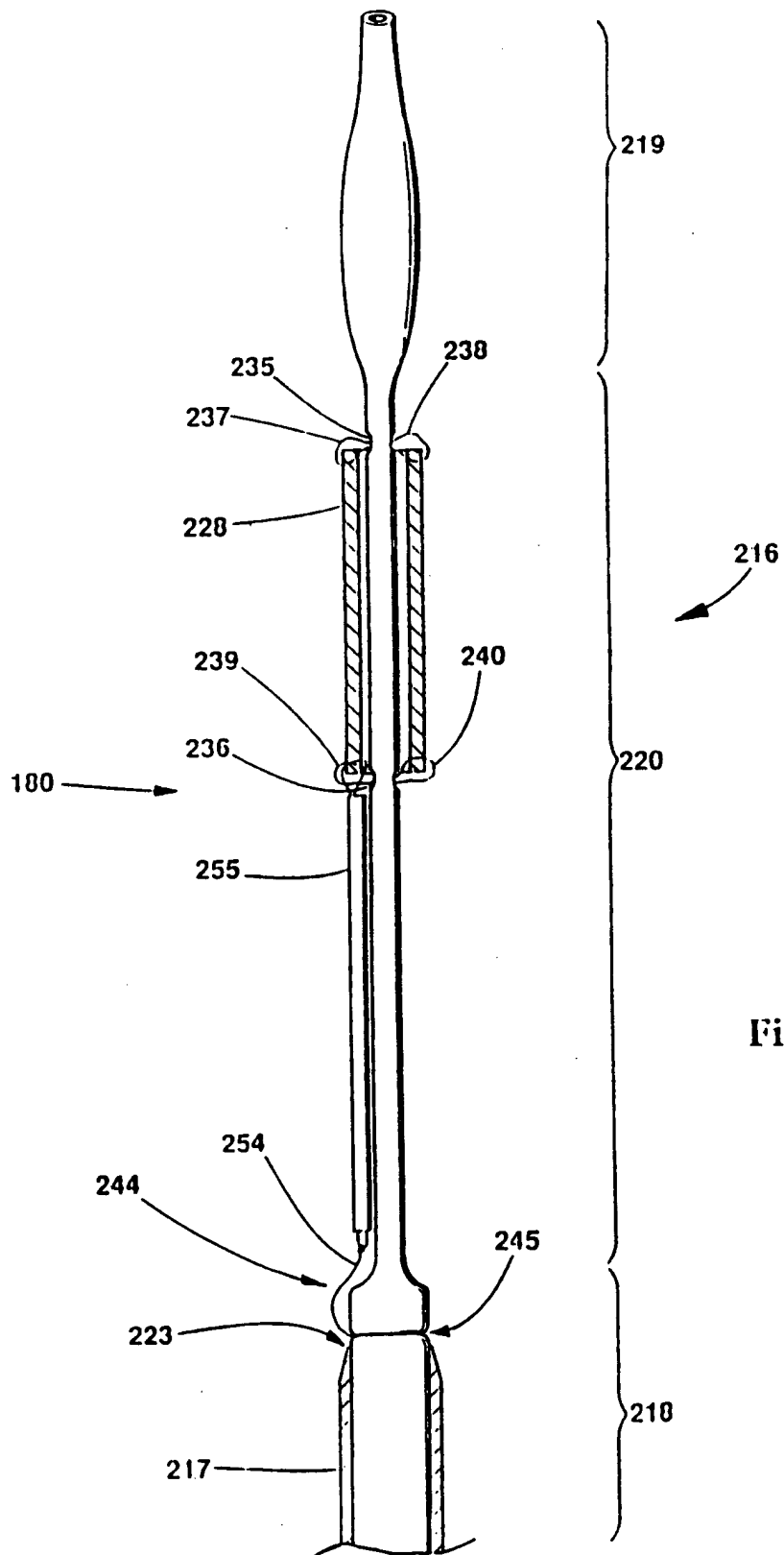
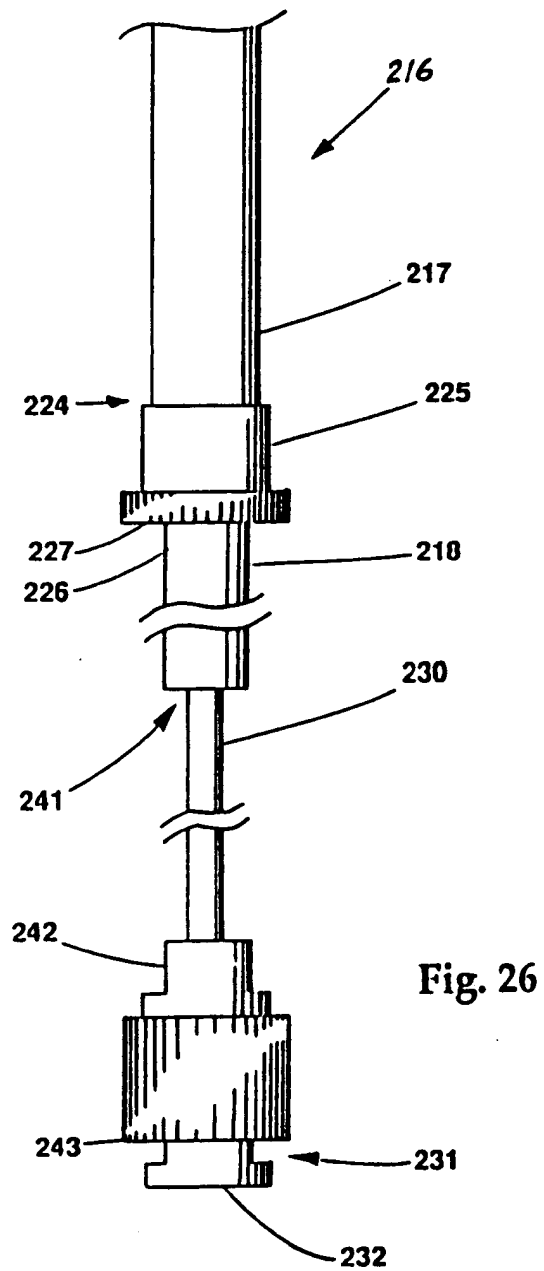
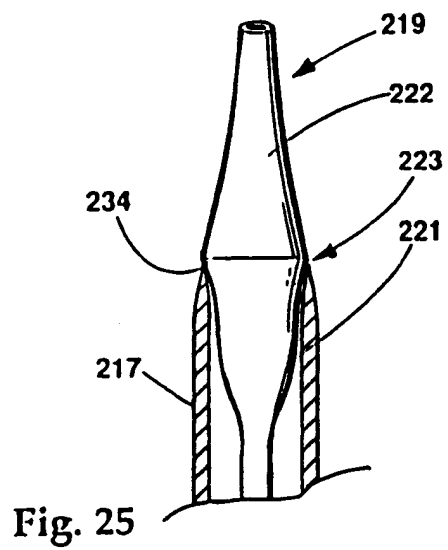
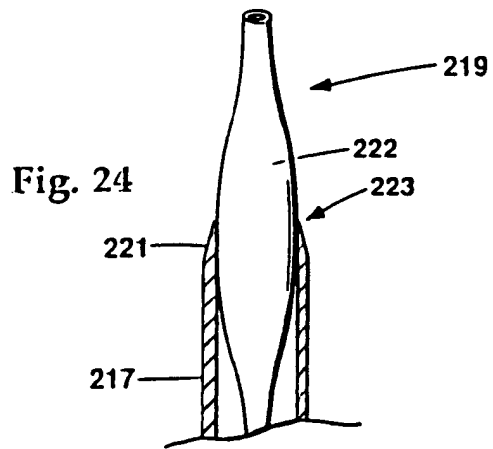


Fig. 20







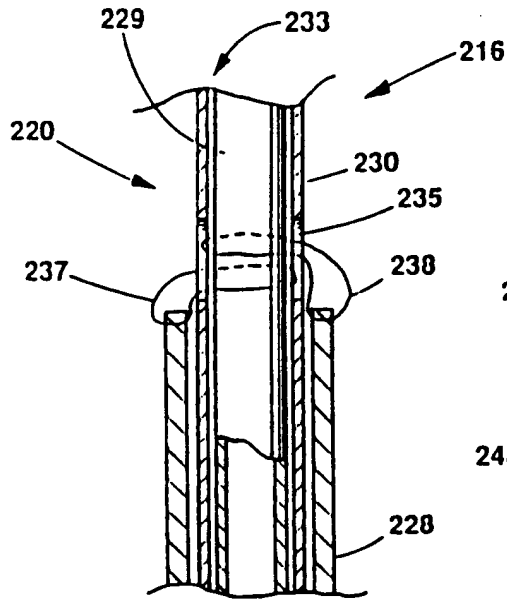


Fig. 27

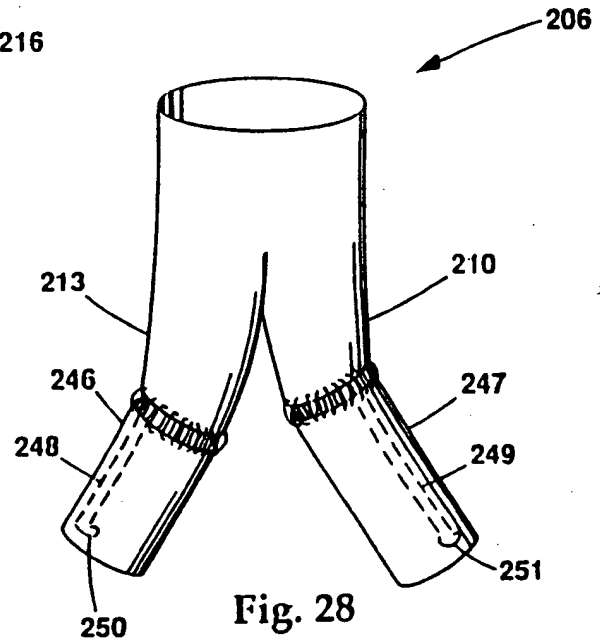


Fig. 28

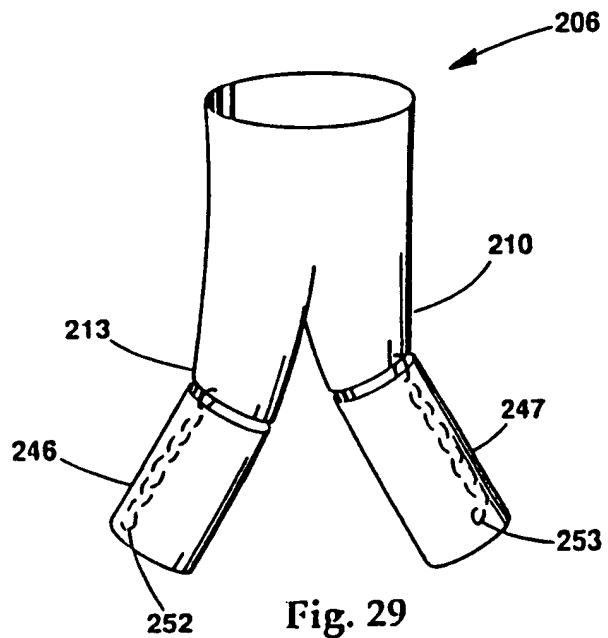
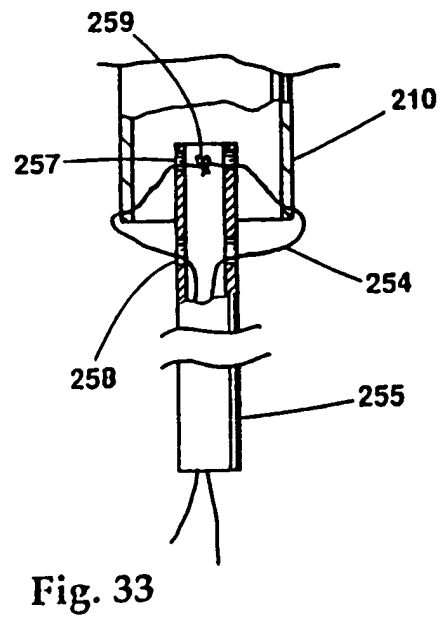
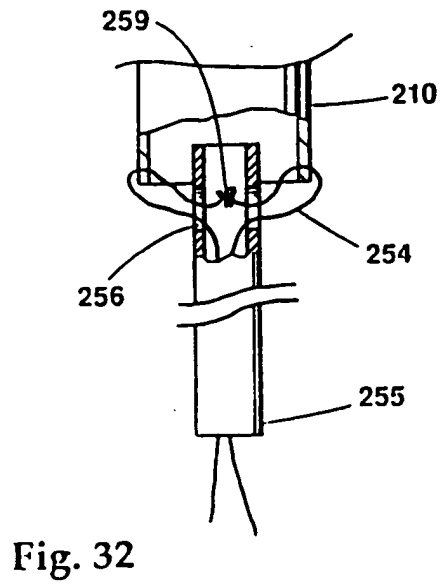
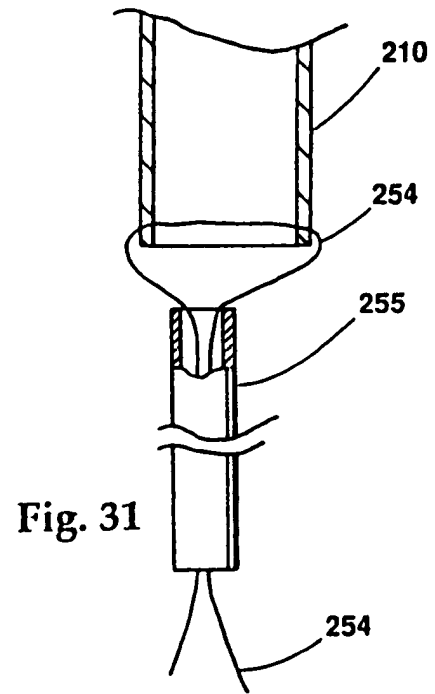
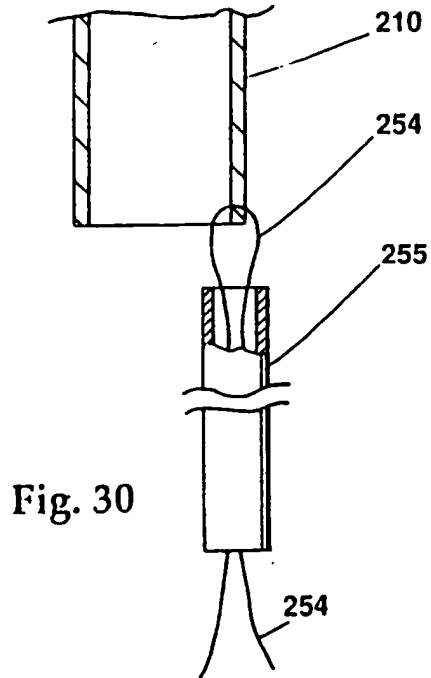


Fig. 29



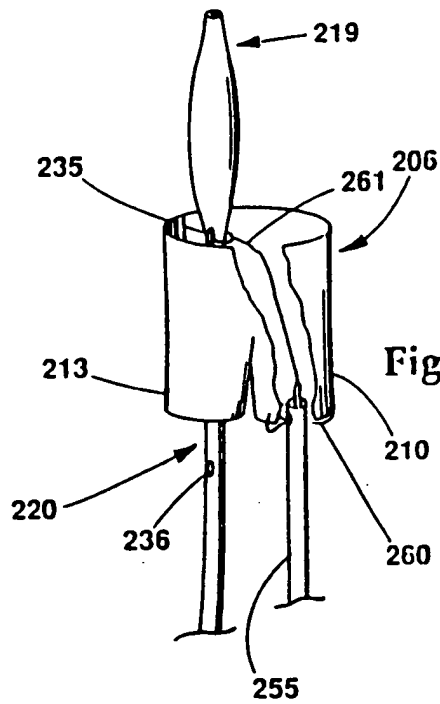


Fig. 34

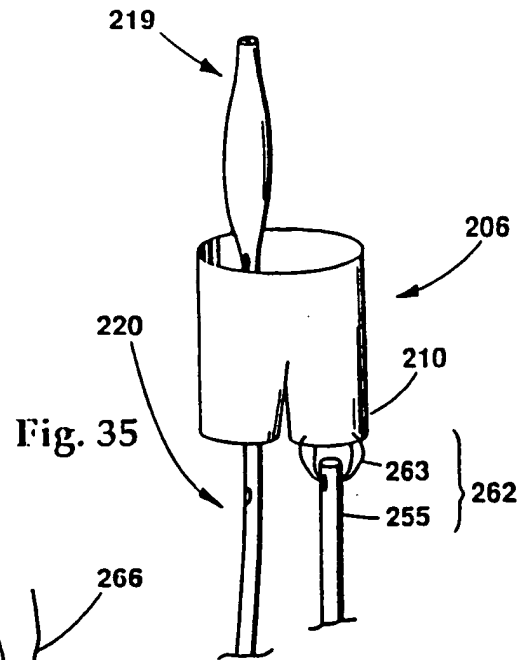


Fig. 35

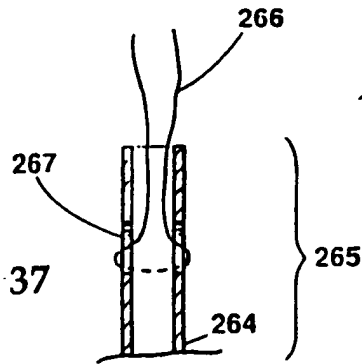


Fig. 37

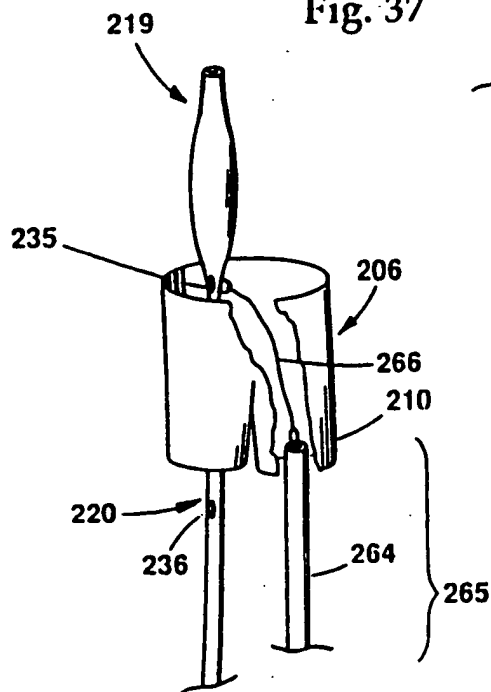


Fig. 36

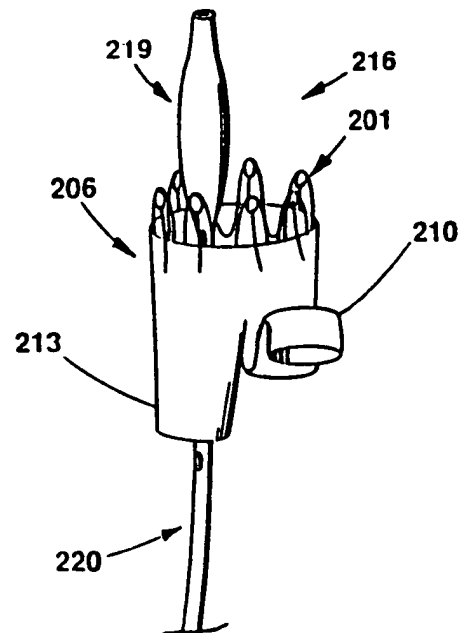


Fig. 38

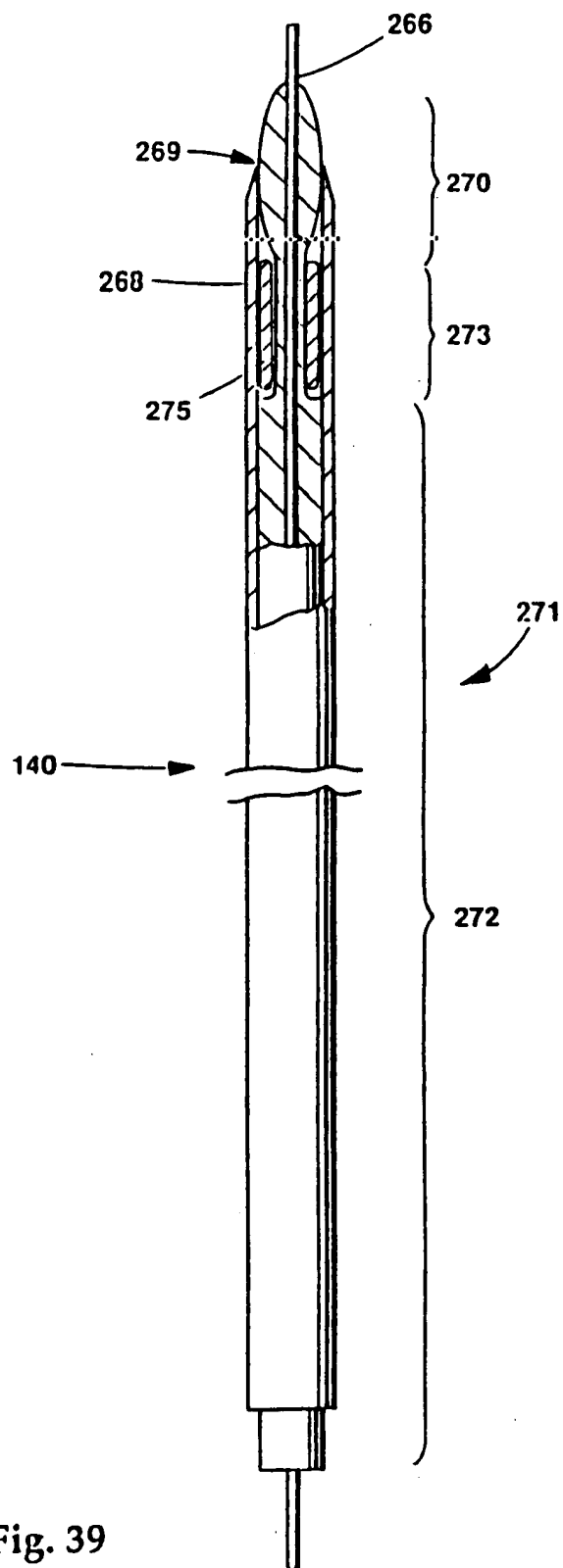


Fig. 39

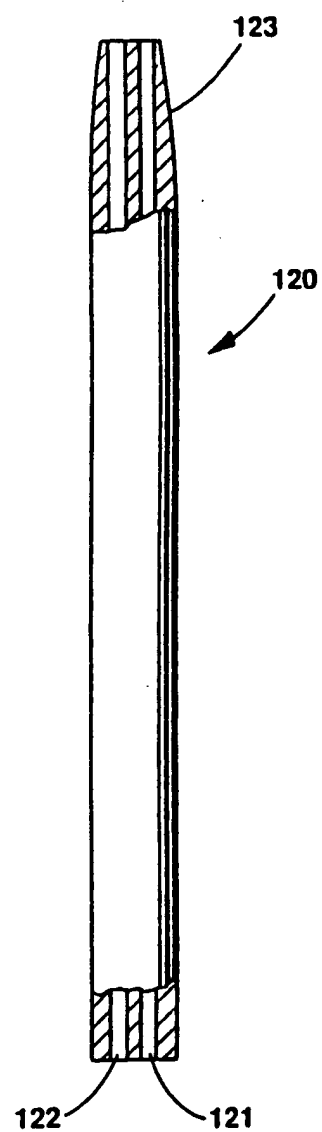
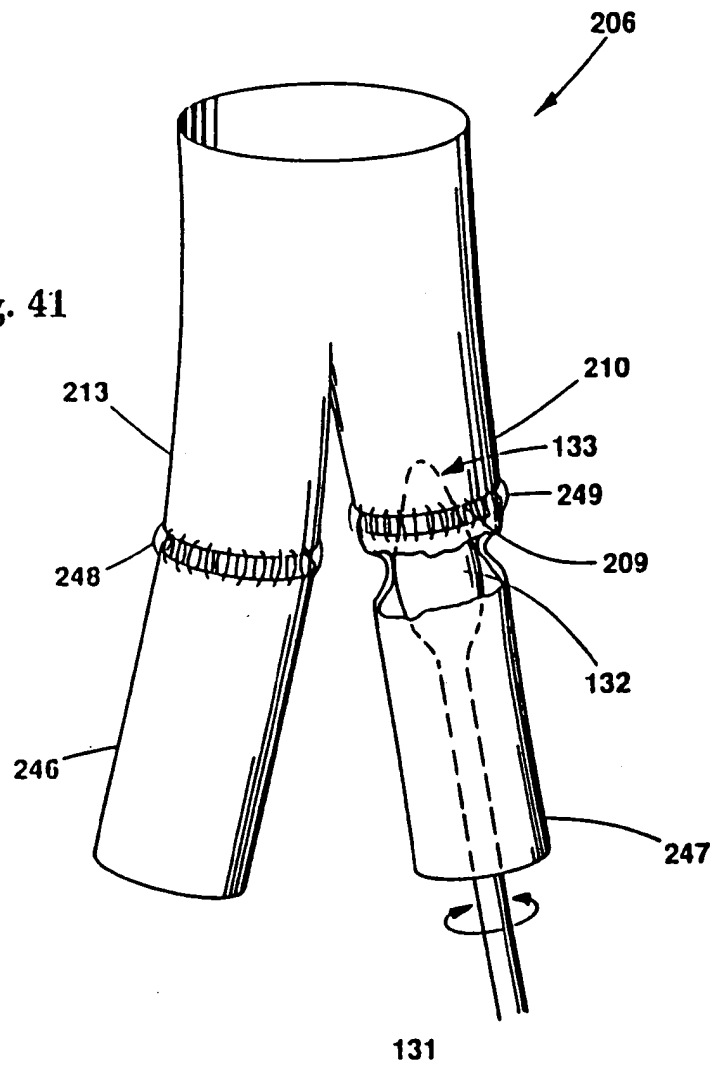


Fig. 42

Fig. 41



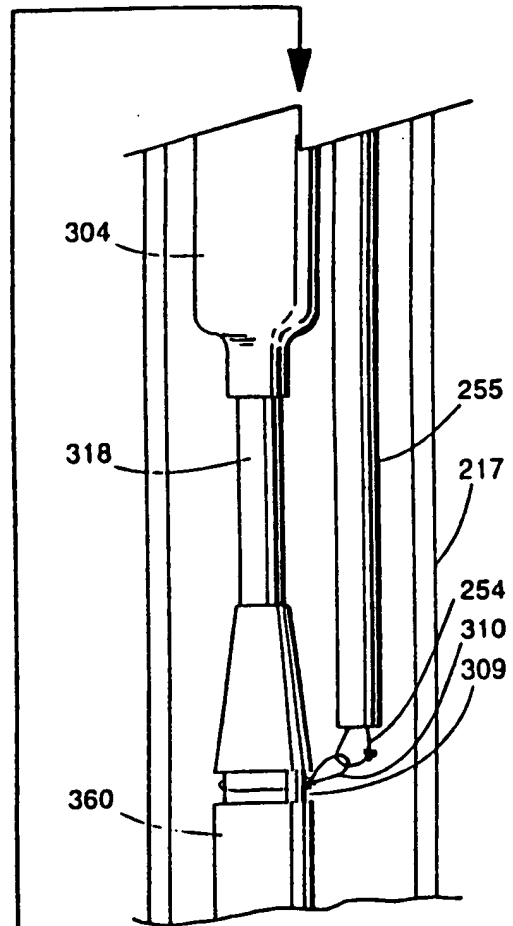
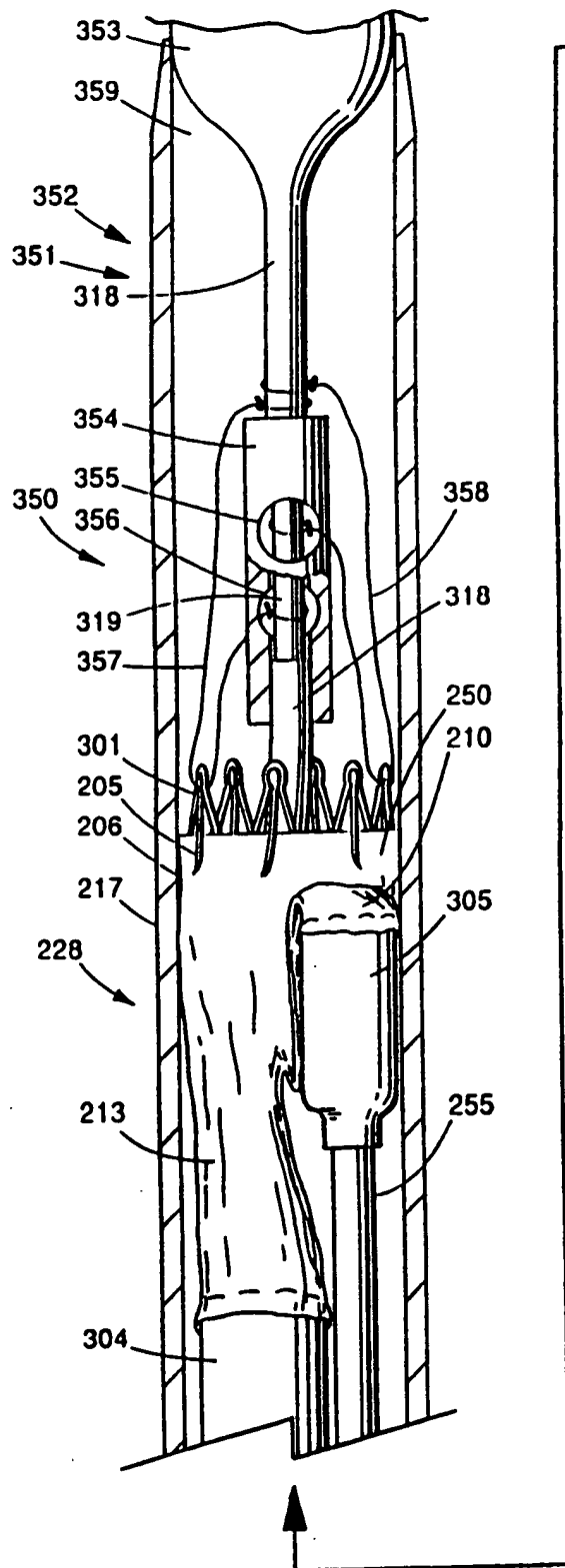


Fig. 43

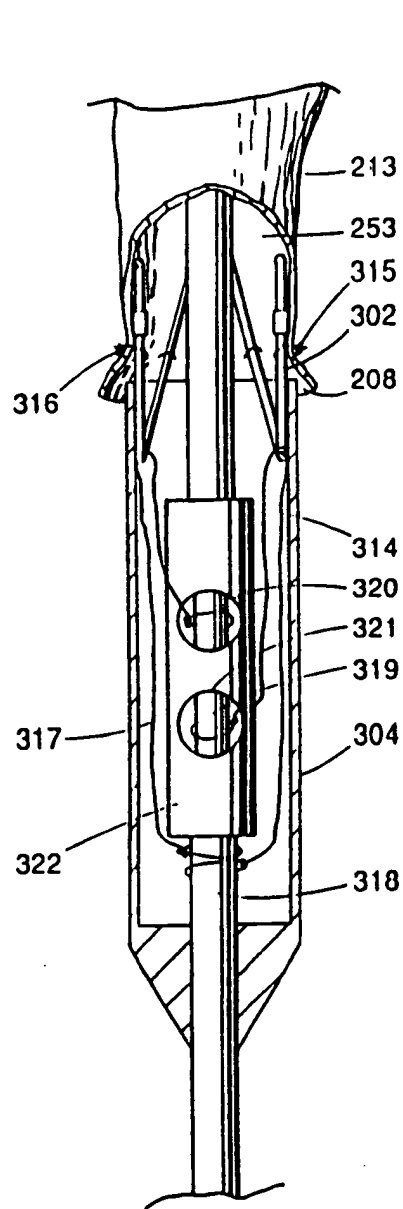


Fig. 44

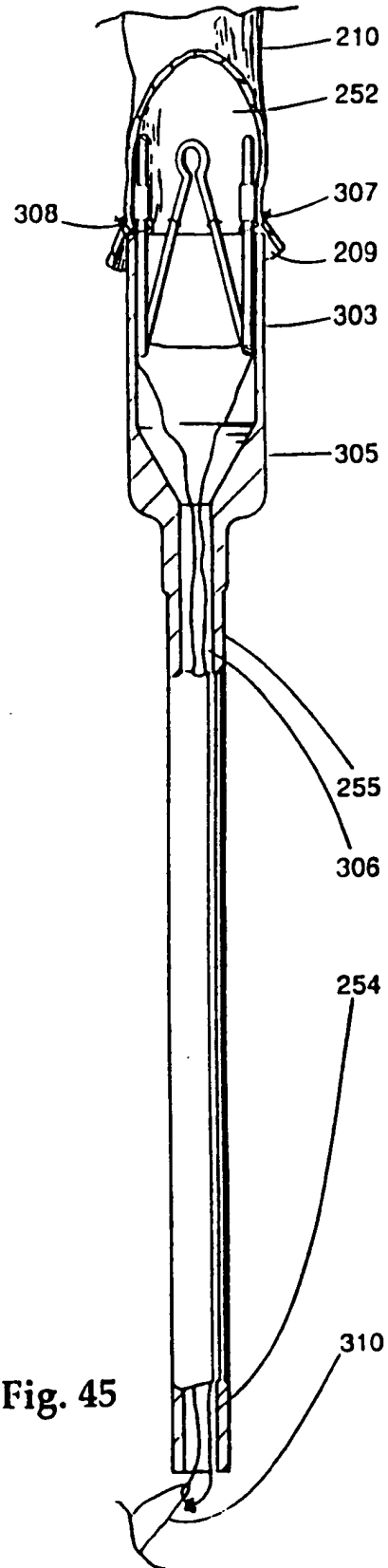


Fig. 45

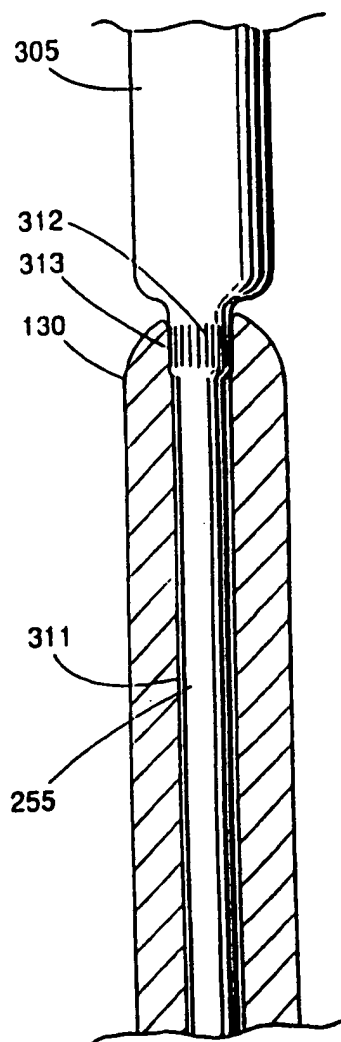
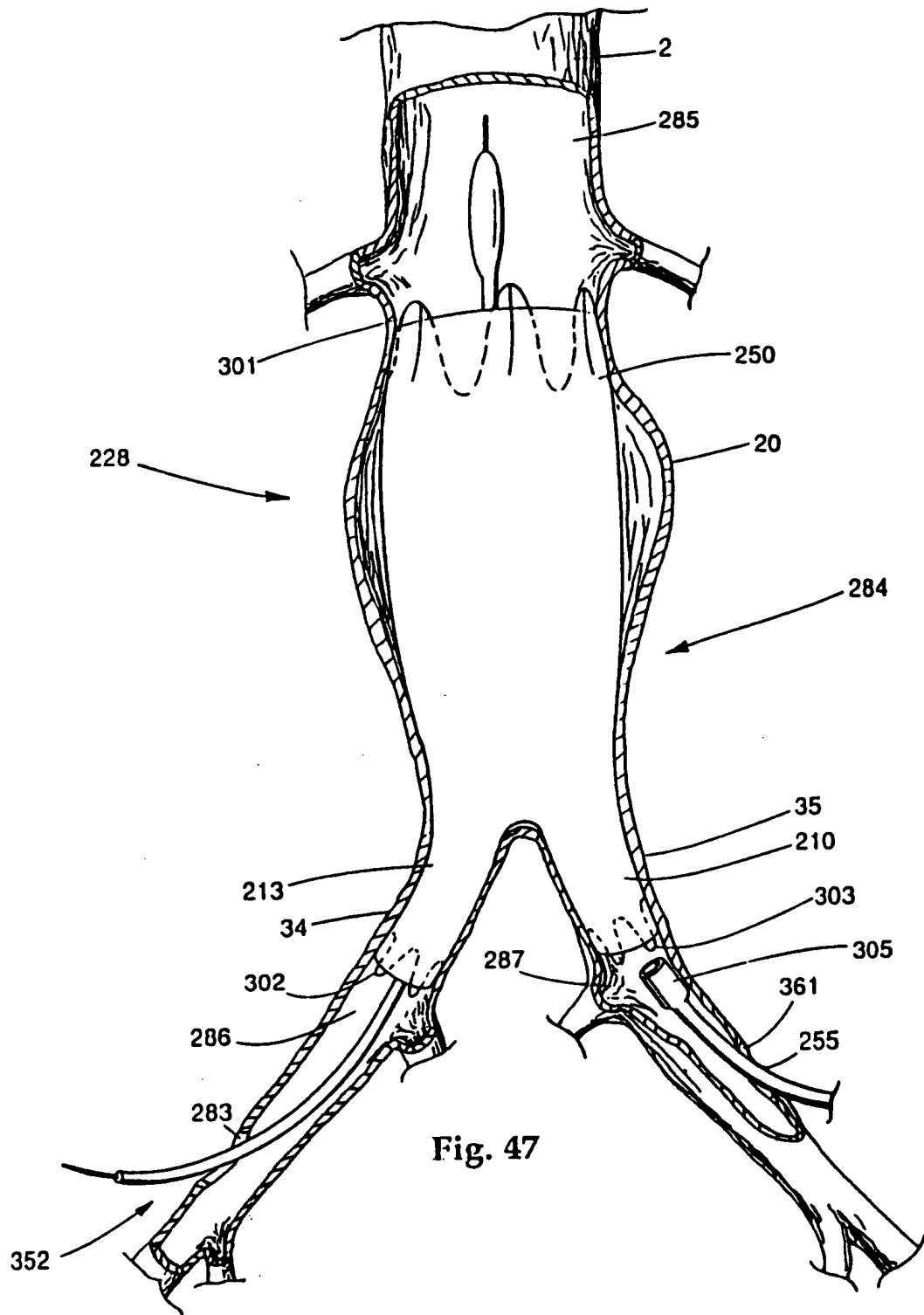


Fig. 46



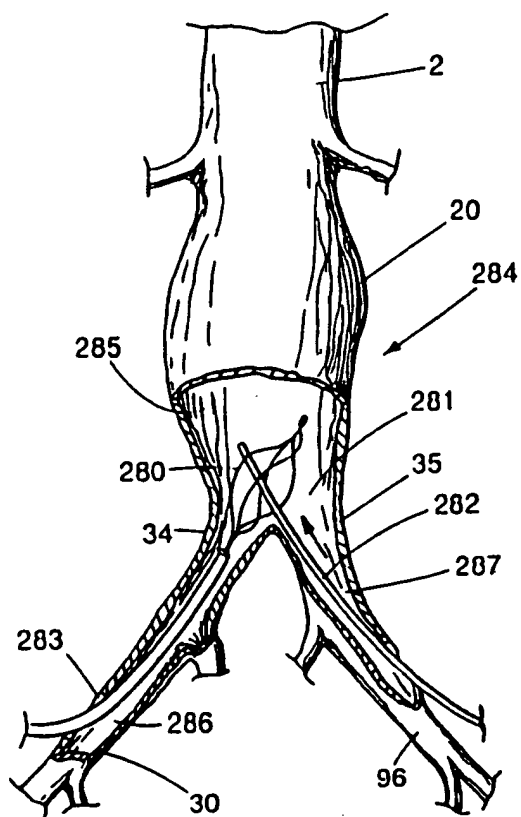


Fig. 48

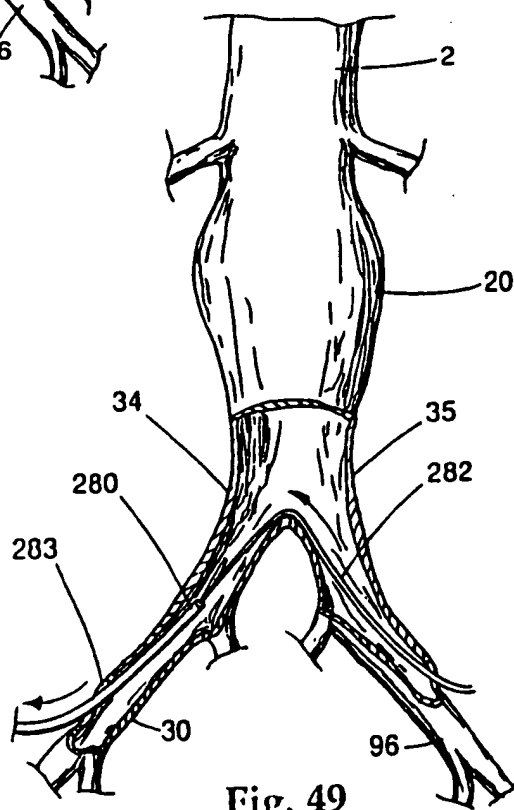
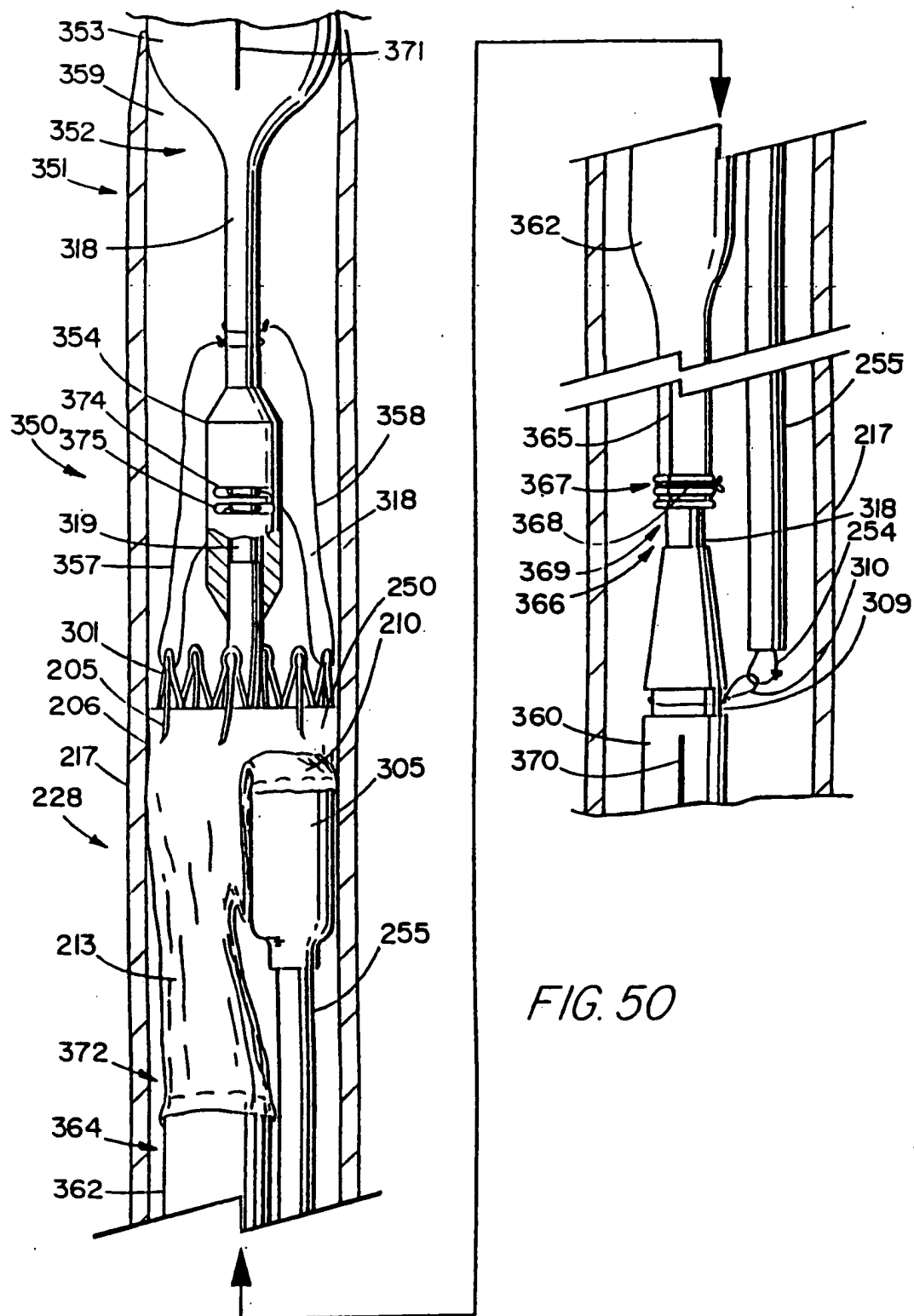


Fig. 49



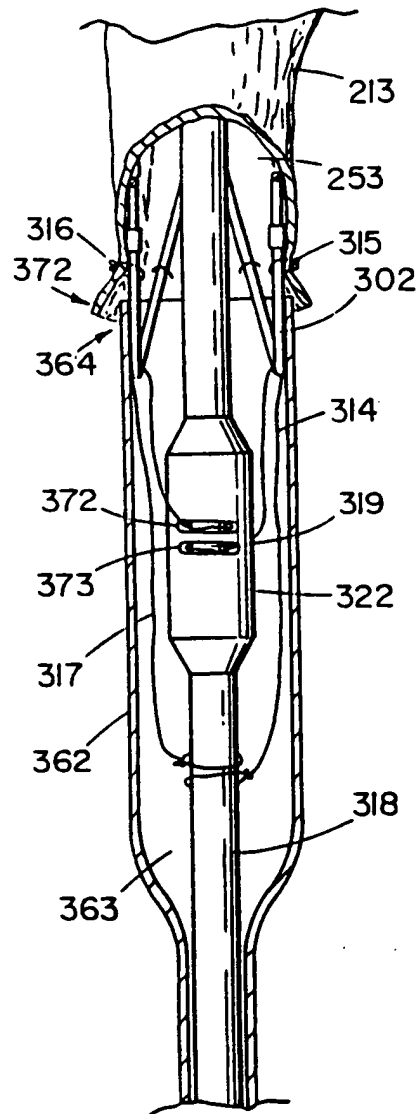


FIG. 51

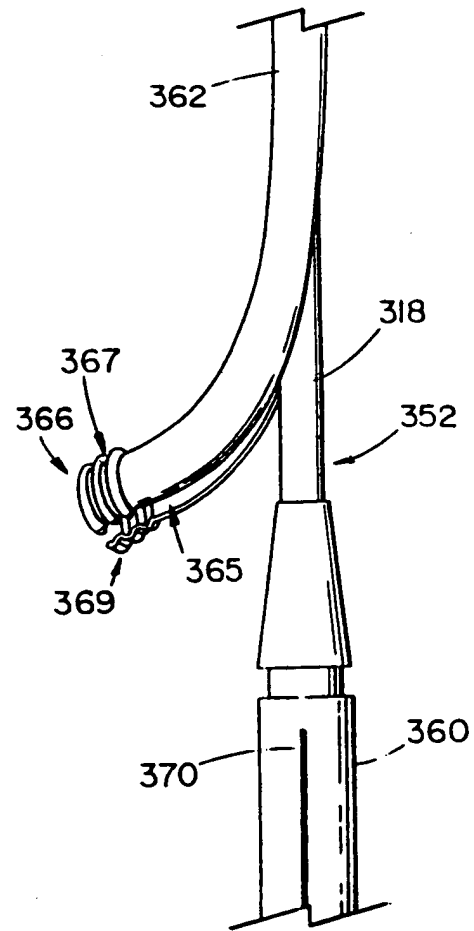


FIG. 52

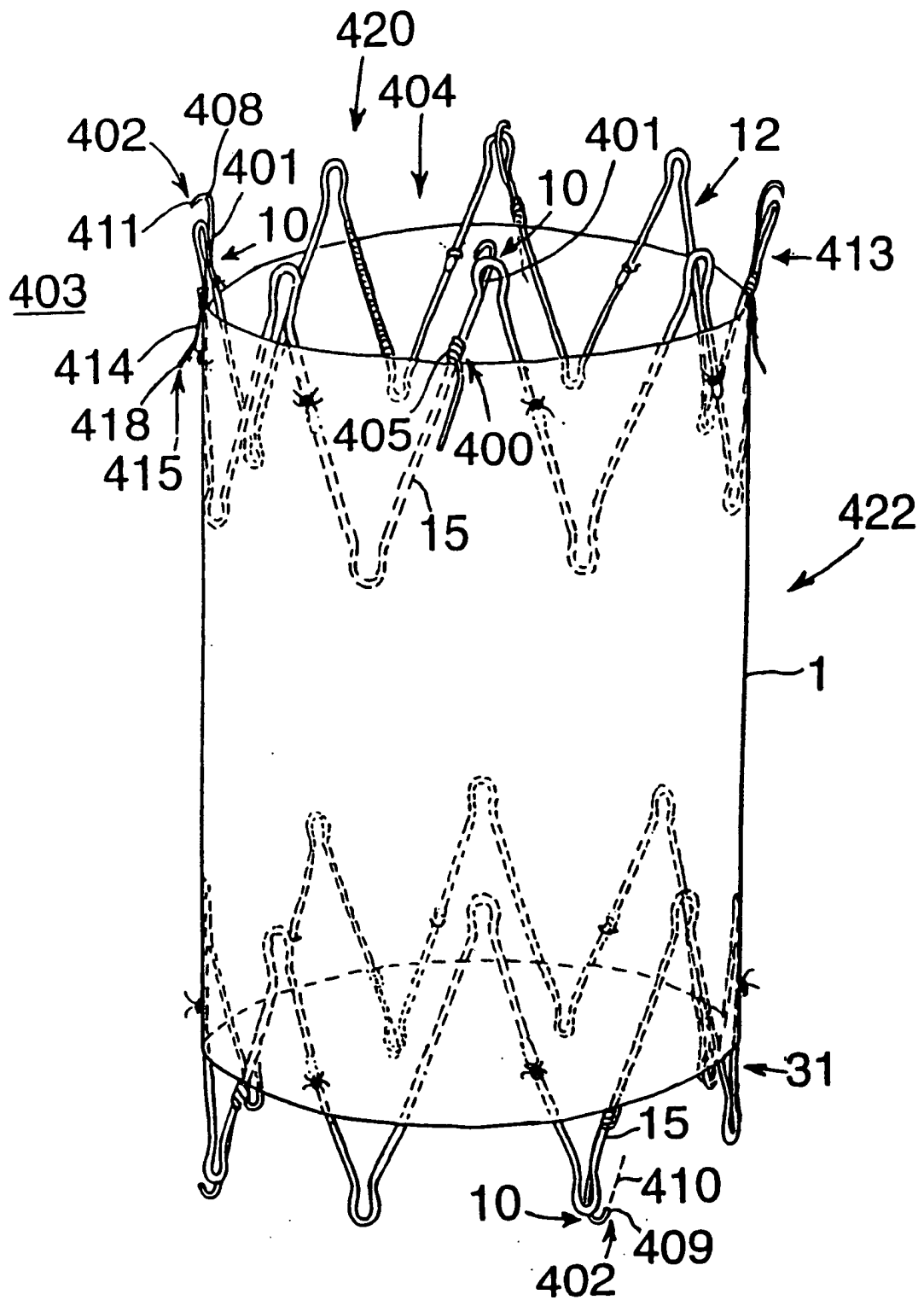


Fig. 53

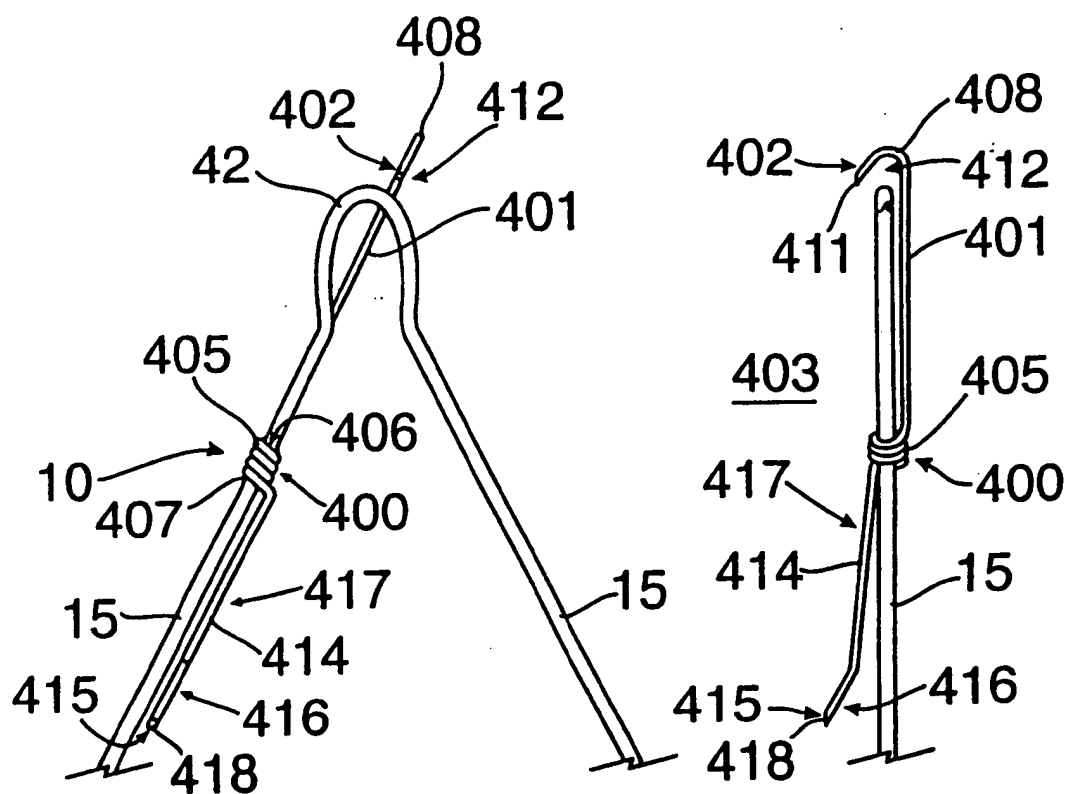


Fig. 54

Fig. 55

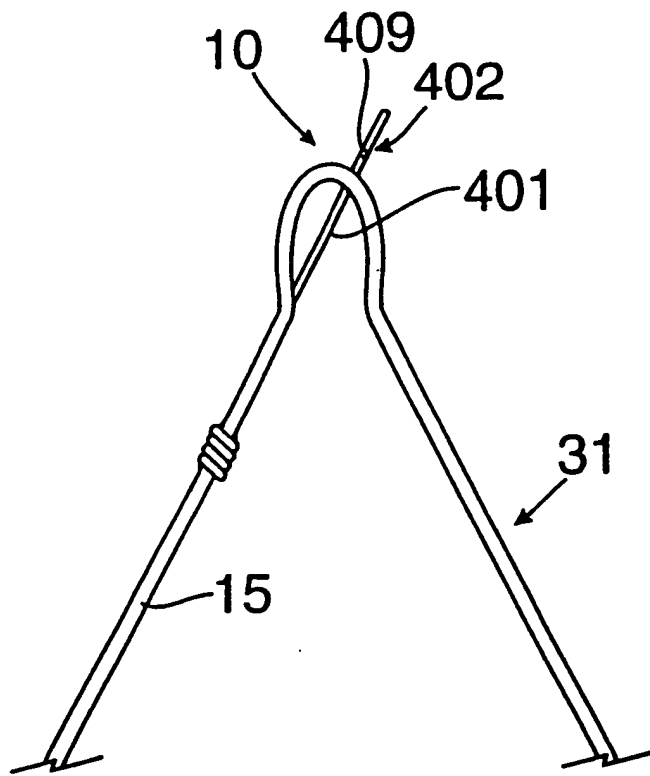


Fig. 57

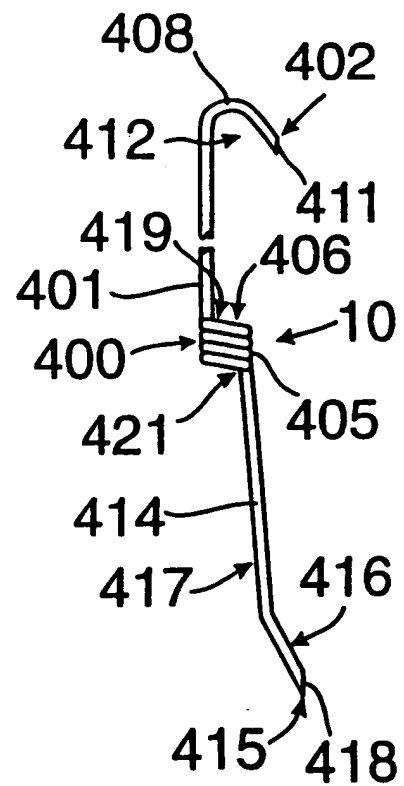


Fig. 56